No. 15-1039
Vide 15-1195

Title:	Sandoz Inc., Petitioner v. Amgen Inc., et al.
Docketed:	February 18, 2016
Linked with 15A672	
Lower Ct:	United States Court of Appeals for the Federal Circuit
Case Nos.:	(2015-1499)
Decision Date:	July 21, 2015
Rehearing Denied:	October 16, 2015

Questions Presented

~~Date~~~	~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~
Dec 23 2015	Application (15A672) to extend the time to file a petition for a writ of certiorari from January 14, 2016 to February 16, 2016, submitted to The Chief Justice.
Dec 29 2015	Application (15A672) granted by The Chief Justice extending the time to file until February 16, 2016.
Feb 16 2016	Petition for a writ of certiorari filed. (Response due March 21, 2016)
Mar 21 2016	Brief amicus curiae of Biosimilars Council filed.
Mar 21 2016	Motion for leave to file amici brief filed by Apotex, Inc., et al.
Mar 21 2016	Brief amici curiae of Hospira, Inc, et al. filed.
Mar 21 2016	Brief of respondents Amgen Inc., et al. in opposition filed.
Mar 21 2016	Brief amicus curiae of Mylan, Inc. filed.
May 31 2016	DISTRIBUTED for Conference of June 16, 2016.
May 31 2016	Reply of petitioner Sandoz Inc. filed. (Distributed)
Jun 20 2016	The Solicitor General is invited to file a brief in this case expressing the views of the United States.
Dec 7 2016	Brief amicus curiae of United States filed. VIDED.
Dec 20 2016	Supplemental brief of respondents Amgen Inc., et al. filed. VIDED.
Dec 21 2016	DISTRIBUTED for Conference of January 6, 2017.
Jan 9 2017	DISTRIBUTED for Conference of January 13, 2017.
Jan 13 2017	Petition GRANTED. The petition for a writ of certiorari in No. 15-1195 is granted. The cases are consolidated and a total of one hour is allotted for oral argument.
Jan 13 2017	Motion for leave to file amici brief filed by Apotex, Inc., et al. GRANTED.
Jan 25 2017	The following briefing schedule is adopted: Petitioner in No. 15-1039 will file an opening brief limited to the question presented in its petition, not to exceed 15,000 words, on or before Friday, February 10, 2017. Petitioners in No. 15-1195 will file a consolidated opening brief on the question presented in their petition and response brief, not to exceed 19,000 words, on or before Friday, March 10, 2017. Petitioner in No. 15-1039 will file a consolidated response brief and reply brief, not to exceed 10,000 words, on or before Friday, March 31, 2017. Petitioners in No. 15-1195 will file a reply brief, not to exceed 6,000 words, on or before Friday, April 14, 2017. Any brief of an amicus curiae in support of petitioner in No. 15-1039 or in support of neither party is to be filed on or before Friday, February 17, 2017, and the brief should bear a light green cover. Any brief of an amicus

	curiae in support of petitioners in No. 15-1195 is to be filed on or before Friday, March 17, 2017, and the brief should bear a dark green cover. An amicus curiae may file only a single brief in these cases. VIDED.
Jan 30 2017	Joint motion of the parties to dispense with printing the joint appendix filed. VIDED.
Feb 10 2017	Brief of petitioner Sandoz Inc. filed.
Feb 17 2017	SET FOR ARGUMENT ON Wednesday, April 26, 2017. VIDED.
Feb 17 2017	Brief amicus curiae of Adello Biologics, LLC filed.
Feb 17 2017	Brief amici curiae of Pharmaceutical Care Management Association, et al. filed.
Feb 17 2017	Brief amici curiae of Apotex Inc. and Apotex Corp. filed. VIDED.
Feb 17 2017	Brief amicus curiae of Biosimilars Council filed. VIDED.
Feb 17 2017	Brief amicus curiae of America's Health Insurance Plans filed. VIDED.
Feb 17 2017	Brief amicus curiae of United States filed. VIDED.
Feb 17 2017	Brief amici curiae of AARP Foundation, et al. filed.
Feb 17 2017	Brief amicus curiae of Coherus Biosciences, Inc. filed. VIDED.
Feb 17 2017	Brief amicus curiae of Mylan, Inc. filed. VIDED.
Feb 21 2017	Motion to dispense with printing the joint appendix filed by petitioners GRANTED. VIDED
Feb 24 2017	Record requested from the U.S.C.A. for the Federal Circuit. VIDED.
Mar 10 2017	Opening and Response Brief for Amgen Inc., et al. filed. VIDED.
Mar 17 2017	Brief amicus curiae of AbbeVie Inc. filed. VIDED.
Mar 17 2017	Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed. VIDED.
Mar 17 2017	Brief amicus curiae of Janssen Biotech, Inc. filed. VIDED.
Mar 17 2017	Brief amicus curiae of Biotechnology Innovation Organization filed. VIDED.
Mar 17 2017	Brief amicus curiae of Genentech, Inc. filed. VIDED.
Mar 22 2017	CIRCULATED.
Mar 27 2017	Record received from the U.S.C.A. for the Federal Circuit. The record is available on PACER, except for confidential materials transmitted separately. VIDED.
Mar 31 2017	Consolidated Response and Reply Brief for Sandoz Inc. Filed. (Distributed) VIDED.
Apr 13 2017	Motion of the Acting Solicitor General for leave to participate in oral argument as amici curiae and for divided argument GRANTED. VIDED. Justice Gorsuch too no part in the consideration or decision of this motion.
Apr 26 2017	Argued. For petitioner in No. 15-1039: Deanne E. Maynard, Washington, D. C.; and Anthony A. Yang, Assistant to the Solicitor General, Department of Justice, Washington, D. C. (for United States, as amicus curiae.) For petitioners in 15-1195: Seth P. Waxman, Washington, D. C. VIDED.
Jun 12 2017	Adjudged to be VACATED IN PART, REVERSED IN PART, and case REMANDED. Thomas, J., delivered the opinion for a unanimous Court. Breyer, J., filed a concurring opinion. VIDED.
Jul 14 2017	JUDGMENT ISSUED.

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RECORD AND BRIEFS

15-1039 No.

FEB 16 2016

In The

Supreme Court of the United States

SANDOZ INC., PETITIONER,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Congress created an abbreviated regulatory pathway for the Food and Drug Administration ("FDA") to license "biosimilar" products—i.e., products that are "highly similar" to approved biological products. 42 U.S.C. § 262(i)(2). The BPCIA's "Notice of commercial marketing" provision states that a biosimilar applicant shall provide notice to the incumbent seller of the biological product "not later than 180 days *before the date of the first commercial marketing* of the biological product licensed under" this abbreviated pathway. *Id.* § 262(*l*)(8)(A) (emphasis added).

The Federal Circuit concluded that a biosimilar applicant "may only give effective notice of commercial marketing *after* the FDA has licensed its product." App., *infra*, 20a (emphasis added). As the dissenting judge recognized, the Federal Circuit turned this mere notice provision into a grant of 180 days of additional exclusivity for all biological products beyond the exclusivity period Congress expressly provided—delaying the launch of all future biosimilars by six months. The Federal Circuit transformed the notice provision into a stand-alone requirement unconnected to the patent resolution provisions of the BPCIA. It also disregarded the only remedy provided by Congress—the right to initiate

QUESTIONS PRESENTED—Continued

patent litigation—and instead created its own extra-statutory injunctive remedy to bar the launch of FDA-approved biosimilars.

The questions presented are:

Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(*l*)(8)(A) as a stand-alone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper.

PARTIES TO THE PROCEEDING AND RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The parties to the proceeding are listed in the caption.[1]

Pursuant to Rule 29.6, petitioner Sandoz Inc. states the following:

Sandoz Inc. is an indirect, wholly owned subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

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[1] Amgen Inc. and Amgen Manufacturing Limited are both respondents in this Court. This petition refers to those entities collectively as "Amgen."

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Sandoz Inc. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-55a) is reported at 794 F.3d 1347. The opinion of the district court (App., *infra*, 56a-84a) is unreported but is available at 2015 WL 1264756.

JURISDICTION

The court of appeals entered judgment on July 21, 2015. Timely rehearing petitions were denied on October 16, 2015. App., *infra*, 85a-86a. On December 29, 2015, the Chief Justice extended the time for Sandoz to petition for a writ of certiorari to and including February 16, 2016. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The BPCIA, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010), and the relevant provisions of Titles 28, 35, and 42 of the United States Code amended by the BPCIA are reprinted in the appendix. App., *infra*, 87a-163a. Section 262(*l*)(8)(A) of Title 42 provides:

> **(A) Notice of commercial marketing**
>
> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

INTRODUCTION

Congress enacted the BPCIA as part of the Patient Protection and Affordable Care Act to create competition in the biologic pharmaceuticals market and to reduce prices. Biologics are used to treat numerous medical conditions. *See* 42 U.S.C. § 262(i)(1). In contrast to chemically synthesized drugs, biologics "are isolated from a variety of natural sources—human, animal, or microorganism." FDA, *What are "Biologics" Questions and Answers*.[1] Biologics "often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available." *Ibid.*

Biosimilars are "highly similar" to approved biological products, which the BPCIA refers to as "reference product[s]." 42 U.S.C. § 262(i)(2). The development of a biosimilar version of a biologic is generally much more expensive and time-consuming than the development of a generic version of a chemically synthesized drug. A Federal Trade Commission ("FTC") report estimates that biosimilars are "likely to take eight to ten years to develop, and their development will likely cost between $100 and $200 million"—in contrast to the three to five years and $1 to $5 million it typically costs to develop a generic

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[1] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm (last visited Feb. 12, 2016).

version of a chemically synthesized drug. FTC, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* iii (June 2009) ("FTC Report").[2]

When Congress passed the BPCIA, purchases of biologics represented 21% of the $307 billion spent annually on medicines, and spending on biologics was increasing materially. CA JA A389-A391. The record before Congress showed that more competition in the biologics market could save government and private payors tens of billions of dollars. *E.g.*, Judith A. Johnson, Cong. Research Serv., RL34045, *FDA Regulation of Follow-On Biologics* 4 (2010).[3] Before the BPCIA's enactment, the FTC predicted that biosimilars would enter the market "at price discounts between 10 and 30 percent" off the reference product's price, and that the incumbent seller of the biological product—called the "reference product sponsor" in the BPCIA—would "respond aggressively and offer competitive discounts." FTC Report, *supra*, at 23. The Congressional Budget Office ("CBO") estimated that the introduction of biosimilars "would reduce total expenditures on biologics in the United States * * * by about $25 billion over the 2009-2018 period."

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[2] https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

[3] https://primaryimmune.org/advocacy_center/pdfs/health_care_reform/Biosimilars_Congressional_Research_Service_Report.pdf.

CBO Cost Estimate, *S. 1695: Biologics Price Competition and Innovation Act of 2007* 1 (June 25, 2008).[4] The CBO projected that savings for the federal government alone would be $7 billion from 2010 to 2019. Letter from CBO Dir. Douglas W. Elmendorf to Hon. Nancy Pelosi, Speaker U.S. House of Rep., Table 5 at 10 (Mar. 20, 2010).[5]

To provide more direct competition, the BPCIA created an abbreviated regulatory pathway for FDA approval of biosimilars, allowing a biosimilar applicant to rely in part on the previous approval of the sponsor's reference product. App., *infra*, 4a-5a; 42 U.S.C. § 262(i)(2), (k). At the same time and in order "[t]o balance innovation and price competition," Congress provided sponsors up to twelve years of market exclusivity against follow-on biosimilar products—regardless of whether the sponsor has any valid patent claims covering the biosimilar. App., *infra*, 5a-6a; *see* 42 U.S.C. § 262(k)(7)(A).

Congress also provided for early resolution of patent disputes, by creating new artificial infringement actions that can be brought before FDA approval of a biosimilar and before any actual infringement occurs. Congress did not, however, link FDA approval of biosimilars to the pendency or outcome of any

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[4] https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/94xx/doc9496/s1695.pdf.

[5] https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/costestimate/amendreconprop.pdf.

patent suit. Rather, the FDA can license a biosimilar immediately upon expiration of the statutorily determined exclusivity period for the reference product. For a product sponsor to enjoin the marketing of a competing biosimilar, it must bring a patent infringement suit and make the requisite showing for a patent-based injunction.

In a fragmented decision, the Federal Circuit has disrupted the careful balance struck by Congress between competition and innovation. If not reversed, the Federal Circuit's ruling will delay access by patients to all biosimilars for six months longer than Congress intended. The Federal Circuit reached that result by adding an extra-textual limitation to the BPCIA's "Notice of commercial marketing" provision. That provision calls for "notice to the reference product sponsor not later than 180 days *before the date of the first commercial marketing* of the biological product licensed under subsection (k)," i.e., the abbreviated biosimilar pathway. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). The Federal Circuit held that an applicant "may only give effective notice of commercial marketing *after* the FDA has licensed its product." App., *infra*, 20a (emphasis added).

A majority of the Federal Circuit panel then enforced that erroneous reading by divorcing that provision from the BPCIA's patent resolution regime and replacing the remedies expressly provided in the BPCIA with a new remedy: "a 180-day injunction beyond the express twelve-year statutory exclusivity period." App., *infra*, 43a-44a (Chen, J., dissenting).

As Judge Chen recognized in dissent, the majority effectively awarded sponsors "an extra-statutory exclusivity windfall" of 180 days more than Congress expressly granted. App., *infra*, 44a (Chen, J., dissenting). The Federal Circuit's decision cannot be squared with the BPCIA's text and purpose, and it conflicts with this Court's precedents. As the district court observed, if Congress had wanted to add six months to the statutory exclusivity period, "it could not have chosen a more convoluted method of doing so." App., *infra*, 76a.

By its plain terms, the notice of commercial marketing provision simply calls for 180 days' notice *before* a biosimilar is marketed. Regardless of whether notice is given before or after FDA approval of the biosimilar, the notice would serve the statute's purpose of giving the reference product sponsor at least 180 days to initiate suit. But special notice after FDA approval would be superfluous, as FDA licensure is a public act. The Federal Circuit reached its erroneous conclusion by reading too much into the word "licensed" in subsection (*l*)(8)(A). That adjective merely refers to the biosimilar product that will be marketed, which will be licensed by the time of marketing. Nothing in the text provides that an applicant must wait until the FDA publicly approves its biosimilar, then provide "notice" of its self-evident intent to market that approved biosimilar, and then wait six months more before marketing its product.

The Federal Circuit compounded this error by disconnecting Section 262(*l*)(8)(A) from the BPCIA's

patent resolution regime and by creating a new remedy nowhere provided by the BPCIA: an injunction against commercial marketing until 180 days after post-approval notice is given. If Congress had so intended, it knew how to stay FDA approval for 180 days; it also knew how to authorize injunctions to enforce the notice provision. It did neither. Instead, it provided sponsors with a powerful remedy: a patent suit for artificial infringement that could be brought even before FDA approval. 42 U.S.C. § 262(*l*)(9)(B), (C); 35 U.S.C. § 271(e)(2)(C). Although Amgen brought such a suit, it made no attempt (and still has not) to seek an injunction based on any alleged patent infringement by Sandoz.

Without any such patent showing by Amgen, the plain terms of the BPCIA authorized Sandoz to make its biosimilar filgrastim product Zarxio® immediately available to cancer patients upon FDA approval: (1) Sandoz already had provided Amgen more than 180 days' notice of its intent to market, giving Amgen time to bring suit (which it did) and seek a patent-based injunction (which it did not), and (2) any statutory exclusivity period had expired, as Amgen already had enjoyed 24 years of exclusivity. *See* App., *infra*, 8a-9a. Instead, due to the Federal Circuit's erroneous interpretation of the notice of commercial marketing provision, competition was excluded from the market well beyond the exclusivity period granted by Congress, and cancer patients had to wait many months *after* FDA approval of Sandoz's product for access to more affordable medicine.

This issue is critically important. As one of the several amici supporting Sandoz's en banc petition explained, "the provision at issue here is a key element of a key statute governing an industry at the vanguard of health care delivery in the 21st Century."[6] Absent intervention from this Court, the Federal Circuit's ruling in this case will apply nationwide to delay the availability of *every* FDA-approved biosimilar for six months longer than Congress intended. Given the importance of this issue to patients, payors (including the federal government), and pharmaceutical companies, that delay should not be allowed to persist without this Court's review.

STATEMENT

A. Statutory Background

Congress struck a careful balance in the BPCIA between facilitating prompt access to cost-saving biosimilars and promoting innovation in biological products. BPCIA § 7001(b), 124 Stat. at 804 (reproduced at App., *infra*, 87a-126a). The statute allows an applicant to rely in part on the sponsor's license for the approved reference product in order to speed biosimilar market entry. 42 U.S.C. § 262(k). In exchange, the BPCIA gives biologics sponsors a total of 12 years without biosimilar competition: the FDA cannot "ma[k]e effective" approval of a biosimilar "until the date that is 12 years after the date on

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[6] Hospira, Inc., et al. *Amici Curiae* Br., CAFC Dkt. No. 140, at 4.

which the reference product was first licensed" by the FDA. *Id.* § 262(k)(7)(A).

The BPCIA also facilitates early resolution of potential patent disputes in order to speed biologics to market. To this end, the BPCIA made interlocking amendments to Titles 28, 35, and 42 of the United States Code. Pub. L. No. 111-148, 124 Stat. 804 (codified at 28 U.S.C. § 2201(b); 35 U.S.C. § 271(e)(2)(C), (4)(D), (6); 42 U.S.C. § 262(k)-(m)) (reproduced at App., *infra*, 127a-163a). In particular, the BPCIA amended the Patent Act to make submission of a biosimilar application to the FDA an artificial act of infringement under certain circumstances. 35 U.S.C. § 271(e)(2)(C). That provision allows a declaratory judgment action on patent infringement and validity before any actual infringement is imminent. *Cf. Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (discussing Congress's creation of an "artificial act of infringement" in order to "enable the judicial adjudication" of patent claims). Who can bring such an action, when, and for what relief depends on the actions or inactions at each step of a multi-step information exchange process between the applicant and the sponsor regarding the sponsor's possible patent claims. 35 U.S.C. § 271(e)(2)(C), (4), (6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(*l*)(2)-(9).

Congress spelled out the actions the applicant or sponsor "shall" take to start and continue the process. Under the first step of the exchange process, the applicant provides a copy of its biosimilar application to the sponsor within 20 days after the FDA accepts

the application for review. 42 U.S.C. § 262(*l*)(2)(A). In later steps, the parties exchange lists of patents for which they believe a claim of patent infringement could reasonably be asserted; exchange their respective positions on infringement, validity, and enforceability; and negotiate regarding the patents for which an immediate infringement action may be brought. *Id.* § 262(*l*)(3)-(5).

Congress also spelled out exactly what happens if a party declines to follow a particular step in the information exchange process. For example, if the applicant does not take the first step (i.e., provide its biosimilar application to the sponsor within 20 days of its acceptance by the FDA), the BPCIA expressly lays out a separate path for resolving any patent disputes: patent infringement litigation, with the scope and timing at the sole discretion of the reference product sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). And even if the patent exchange process is initiated, and regardless of whether it is completed, the end result is that the reference product sponsor or the applicant can bring suit for patent infringement. The contours of that suit are determined by the actions that the parties did or did not take in the information exchange process. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (9)(A)-(B).

As particularly relevant to this petition, the BPCIA includes a provision entitled "Notice of commercial marketing." 42 U.S.C. § 262(*l*)(8)(A). That provision states:

> The subsection (k) applicant [i.e., the biosimilar applicant] shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k) [i.e., the biosimilar product].

Ibid. This provision provides notice to the sponsor that a biosimilar is at least six months from coming to market and allows the sponsor to seek a preliminary injunction to enforce any patent claims it has not yet been able to enforce in the exchange process. *Id.* § 262(*l*)(8)(A)-(B).

Critically, the BPCIA also expressly specifies a consequence for not providing the notice of commercial marketing. Where the applicant has initiated the patent exchange process and the sponsor has provided its initial list of possibly relevant patents to the applicant, the consequence of the applicant's not providing the notice is that "the reference product sponsor, but not the [biosimilar] applicant, may bring an action" for a declaration of infringement, validity, or enforceability of any patent on that list. *Id.* § 262(*l*)(9)(B). And where the applicant did not initiate the patent exchange process by providing its biosimilar application, that non-provision of the application already had triggered the sponsor's ability to bring an action for a declaration of infringement of any patent. *See* 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C).

B. Factual Background

1. Sandoz's biosimilar application

When Sandoz applied for FDA approval of its filgrastim biosimilar, Amgen already had marketed filgrastim under the brand name Neupogen® for 24 years—twice the 12-year period Congress deemed sufficient to encourage innovation in biologics. App., *infra*, 8a; 42 U.S.C. § 262(k)(7)(A).

On July 7, 2014, the FDA accepted for review Sandoz's application for biosimilar filgrastim. App., *infra*, 8a. The next day, Sandoz notified Amgen that Sandoz had filed the application and that Sandoz expected FDA approval in the first half of 2015. *Ibid.* Sandoz also provided notice that it intended to launch its biosimilar filgrastim product in the United States immediately upon FDA approval. *Ibid.* The FDA had publicly stated a goal of reviewing and acting on a majority of biosimilar applications within 10 months of receipt. *See* FDA, *Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 Through 2017* 3.[7]

In light of Amgen's public statements in filings with the Securities and Exchange Commission that it had no material, unexpired patents for filgrastim, Sandoz determined that subjecting itself to an immediate patent suit was the quickest path to resolution

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[7] http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf.

of any patent claims. CA JA A915, A960, A1495-A1497. On July 25, 2014, Sandoz therefore informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and that the BPCIA thus entitled Amgen to bring a declaratory judgment action for patent infringement against Sandoz. App., *infra*, 8a; *see* 42 U.S.C. § 262(*l*)(9)(C).

2. Proceedings in district court

a. Several months later—in October 2014—Amgen sued Sandoz, asserting three claims. App., *infra*, 9a.

First, Amgen brought a claim under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, which provides a cause of action against "any unlawful, unfair or fraudulent business act or practice." App., *infra*, 26a. Amgen alleged that Sandoz committed "unlawful" acts for purposes of the UCL by violating the BPCIA. App., *infra*, 9a. Specifically, Amgen alleged that Sandoz violated the BPCIA (1) by not providing Amgen its application within 20 days of FDA's acceptance of Sandoz's application and (2) by giving an allegedly premature, ineffective notice of commercial marketing before FDA approval. *Ibid.*

Second, Amgen brought a state law claim for conversion, alleging that Sandoz wrongfully used Amgen's approved license for Neupogen®. *Ibid.*

Third, expressly invoking the recourse provided by the BPCIA, 42 U.S.C. § 262(*l*)(9)(C), Amgen brought a claim for artificial infringement of Amgen's U.S. Patent No. 6,162,427 ("'427 patent"), which claims a method of treating a patient using filgrastim. App., *infra*, 9a. Amgen, however, did not seek (and still has not sought) an injunction based on purported patent infringement.

Sandoz counterclaimed, seeking declaratory judgments concerning the correct interpretation of the BPCIA and for non-infringement and invalidity of the '427 patent. *Ibid.*

b. On March 6, 2015, the FDA approved Sandoz's biosimilar filgrastim product Zarxio®, the first biosimilar approved under the BPCIA. App., *infra*, 8a-9a. Although Sandoz "maintained that it gave an operative notice of commercial marketing in July 2014"—the day after filing its biosimilar application, *see supra* p. 12—Sandoz "nevertheless gave a 'further notice of commercial marketing' to Amgen on the date of FDA approval." App., *infra*, 9a.

c. On March 19, 2015, the district court denied Amgen's motions for judgment on the pleadings and for a preliminary injunction and granted Sandoz's motion for judgment on Amgen's state law claims and Sandoz's BPCIA counterclaims. App., *infra*, 56a-84a. The court concluded that it was lawful for Sandoz not to provide Amgen its biosimilar application within 20 days of acceptance by the FDA. App., *infra*, 68a-73a.

The district court also concluded that it was lawful for Sandoz to provide its 180-day notice of commercial marketing before FDA approval, meaning that Sandoz's July 2014 notice was effective. App., *infra*, 73a-76a. The court rejected Amgen's argument that the word "licensed" in the notice provision "means an applicant may not give the required 180-day notice to the reference product sponsor until *after* the FDA has granted approval of biosimilarity—resulting in a mandatory 180-day post-FDA approval waiting period prior to biosimilar market entry." App., *infra*, 74a. The district court explained that "licensed" in the provision refers only to the fact that the product must be licensed before marketing and not to "the appropriate time for notice." App., *infra*, 75a. The court further explained that "[e]ven more problematic with Amgen's reading" is that it would "tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A)." App., *infra*, 75a-76a.

d. The district court entered final judgment under Federal Rule of Civil Procedure 54(b) on Amgen's state law claims and Sandoz's BPCIA counterclaims. App., *infra*, 11a. The court granted the parties' joint request to stay all other proceedings, including Amgen's patent infringement claim and Sandoz's patent counterclaims. *Ibid.*

3. Proceedings in the Federal Circuit

a. On May 5, 2015, the Federal Circuit issued an injunction pending appeal, precluding Sandoz from marketing, selling, offering for sale, or importing into the United States its FDA-approved Zarxio® product. App., *infra*, 31a; CAFC Dkt. No. 105.

b. On July 21, 2015, a fractured Federal Circuit panel affirmed the dismissal of Amgen's state law claims for unfair competition and conversion, vacated the judgment on Sandoz's counterclaims, and remanded. App., *infra*, 1a-55a. The court also extended the injunction pending appeal through September 2, 2015—180 days from when the FDA approved Sandoz's filgrastim and Sandoz provided its second notice of commercial marketing. App., *infra*, 31a.

Disclosure of the application. A majority of the panel (Judge Lourie joined by Judge Chen) agreed with Sandoz that, considering the statute as a whole, the BPCIA "explicitly contemplates" that an applicant might not take the first step in the information exchange process: disclosing its application to the sponsor under subsection (*l*)(2)(A). App., *infra*, 15a. As the court explained, the BPCIA "specifically sets forth the consequence for such failure: the [sponsor] may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)." *Ibid.* Both provisions "are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." App., *infra*, 17a. "Because

Sandoz took a path expressly contemplated by the BPCIA," the court held, "it did not violate the BPCIA by not disclosing its [application] and the manufacturing information by the statutory deadline." App., *infra*, 18a. Judge Newman dissented from this part of the decision. App., *infra*, 35a-42a (Newman, J., dissenting).

Notice of commercial marketing. The Federal Circuit interpreted the BPCIA's "[n]otice of commercial marketing" provision to mean that the "applicant may only give effective notice of commercial marketing *after* the FDA has licensed its product." App., *infra*, 20a (emphasis added). As noted, the provision states that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). The Federal Circuit read the phrase "licensed under subsection (k)" to require that notice "be given only after the product is licensed by the FDA," rather than as simply referring to the fact that the biological product will be licensed before marketing. App., *infra*, 20a. Based on this reading of the statute, the court concluded that Sandoz's July 2014 notice of commercial marketing was "premature and ineffective" and that Sandoz's March 2015 notice "serves as the operative and effective notice of commercial marketing in this case." App., *infra*, 23a.

Injunction. In contrast with the majority's conclusion that the BPCIA provided the exclusive consequence for not disclosing a biosimilar application

under subsection (*l*)(2)(A), a second majority (Judge Lourie joined by Judge Newman) did "not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with" the notice of commercial marketing provision in a case, like this one, where the patent exchange process did not take place. App., *infra*, 24a-25a. The majority acknowledged that subsection (*l*)(9)(B) expressly provides that if a biosimilar applicant does not provide its notice of commercial marketing, "'the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent included in the list'" prepared by the sponsor early in the patent exchange process. App., *infra*, 24a-25a (quoting 42 U.S.C. § 262(*l*)(9)(B)) (emphasis by CAFC omitted).

The majority concluded, however, that this consequence "does not apply" where, as here, the biosimilar applicant did not initiate the patent exchange process because the referenced "list" of patents that could be the basis of a declaratory judgment action does not exist. App., *infra*, 25a. The majority further concluded that the notice provision is a "mandatory," "standalone" provision that must be complied with, regardless of whether the applicant has disclosed its application under subsection (*l*)(2)(A). App., *infra*, 25a-26a. It then ruled (without specifying any source of its remedial authority to do so) that "Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015."

App., *infra*, 26a. And the majority fashioned its own injunctive remedy: "In light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended through September 2, 2015"—that is, 180 days from Sandoz's post-approval notice of commercial marketing. App., *infra*, 31a.

Judge Chen dissented from this portion of the decision. App., *infra*, 42a-55a (Chen, J., dissenting). He criticized the majority's reading of the notice provision as giving the reference product sponsor "an extra-statutory exclusivity windfall." App., *infra*, 44a (Chen, J., dissenting). Judge Chen did not "view (*l*)(8)(A) as a 'standalone provision' that provides, implicitly, the [reference product sponsor] a 180-day injunction beyond the express twelve-year statutory exclusivity period." App., *infra*, 43a-44a (Chen, J., dissenting). He noted that Congress knew how to "create a 180-day automatic stay," if it wished to do so. App., *infra*, 52a-53a (Chen, J., dissenting). For example, Congress "could have tied FDA approval to the notice provision" by providing that FDA approval cannot be effective until 180 days after notice is given. App., *infra*, 53a (Chen, J., dissenting).

Judge Chen explained that, "when reading (*l*)(8) in the context of subsection (*l*) as a whole, it becomes clear that (*l*)(8) is simply part and parcel of the integrated litigation management process contemplated in (*l*)(2)-(*l*)(7)." App., *infra*, 43a (Chen, J., dissenting). He would have held that, "when, as here, the

[biosimilar] applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Ibid.* Moreover, recognizing that subsection (*l*) "concerns one thing: patent litigation," App., *infra*, 45a (Chen, J., dissenting), Judge Chen would have held that the BPCIA provides the exclusive consequence for failure to provide 180 days' notice: the reference product sponsor may file a declaratory judgment suit for patent infringement. App., *infra*, 51a-52a (Chen, J., dissenting).

State law claims. The first majority (with Judge Newman dissenting) affirmed the dismissal of Amgen's UCL claim with respect to Sandoz's failure to provide its biosimilar application on the ground that such failure "did not violate the BPCIA" and that the Patent Act "provides 'the only remedies which may be granted by a court' for the alleged violation." App., *infra*, 27a (quoting 35 U.S.C. § 271(e)(4)). The majority found "moot" Amgen's "appeal from the dismissal of its unfair competition claim based on the alleged violation of" the notice of commercial marketing provision on the ground that the court of appeals "will extend the injunction pending appeal through September 2, 2015." App., *infra*, 27a-28a. The court also affirmed dismissal of Amgen's conversion claim because, among other reasons, Amgen "failed to show a 'wrongful act'" on Sandoz's part. App., *infra*, 28a-29a.

d. Sandoz launched its biosimilar filgrastim product Zarxio® in the United States on September 3, 2015.

e. Both Sandoz and Amgen filed petitions for rehearing en banc. App., *infra*, 85a-86a. Sandoz's petition was supported by multiple amici who stressed the importance of this issue: the Biosimilars Council (CAFC Dkt. No. 139), Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc. (CAFC Dkt. No. 140); and Mylan Inc. (CAFC Dkt. No. 150). The Federal Circuit denied en banc review. App., *infra*, 85a-86a.

f. The Federal Circuit remanded to the district court, which lifted the stay on Amgen's patent claims and Sandoz's patent infringement counterclaim. Amgen still has sought no patent-based injunction.

REASONS FOR GRANTING THE PETITION

THE FEDERAL CIRCUIT'S "EXTRA-STATUTORY EXCLUSIVITY WINDFALL" IS CONTRARY TO THE STATUTE'S TEXT AND PURPOSE AS WELL AS THIS COURT'S PRECEDENTS

This Court should grant review because the Federal Circuit has interpreted the BPCIA's notice of commercial marketing provision so as to grant a 180-day "exclusivity windfall" to reference product sponsors. The Federal Circuit's erroneous interpretation will delay the availability of all biosimilars for 180 days more than Congress intended—even if the sponsor has no valid patent claims and even if the sponsor already has had the opportunity to pursue any valid claims. The text and purpose of Section 262(*l*)(8)(A) call for notice 180 days *before* commercial marketing; nothing requires that the applicant wait until *after* FDA approval to provide that notice of commercial marketing. Yet the Federal Circuit read that limitation into the statute. It compounded its error by disconnecting the notice provision from the BPCIA's patent resolution regime and creating an extra-textual injunctive remedy. The Federal Circuit's ruling is contrary to the statute's plain text and purpose and to this Court's precedents. No other court of appeals will review this question; the Federal Circuit has bound the nation. This Court's review of this important federal question is needed now. *See* Sup. Ct. R. 10(c).

A. The Federal Circuit's Post-Approval Limitation Is Contrary To The Text And Purpose Of The Notice Of Commercial Marketing Provision And Conflicts With This Court's Decisions

1. The Federal Circuit's interpretation of Section 262(l)(8)(A) conflicts with the statutory text and upends the provision's purpose

Section 262(*l*)(8)(A) is entitled "Notice of commercial marketing." 42 U.S.C. § 262(*l*)(8)(A). By its plain terms, subsection (*l*)(8)(A) provides only for the applicant to give notice to the product sponsor "180 days before the date of the first commercial marketing" of its biosimilar. *Ibid.* So long as the notice is provided 180 days before the applicant brings its competing biosimilar to market, the plain language of this provision is satisfied. Nothing in the statutory text requires the applicant to wait until after FDA approval, then provide notice that it intends to market, and then wait six months more.

Indeed, Congress knew how to require that an action be both "after" one event and "before" another. It did that in the very next subsection, (*l*)(8)(B): "*After* receiving the notice under subparagraph (A) and *before* such date of the first commercial marketing * * * ." *Id.* § 262(*l*)(8)(B) (emphasis added). Comparable language is markedly absent from subsection (*l*)(8)(A). Congress easily could have provided that notice should be given "*after* receiving FDA approval and 180 days *before* the date of the first commercial marketing"; it did not.

Despite the lack of a requirement in the statute's text that the notice of commercial marketing must be given after FDA approval, the Federal Circuit found such a requirement in the adjective "licensed" in the phrase "the biological product licensed under subsection (k)." *Id.* § 262(*l*)(8)(A). But that phrase just identifies the product whose commercial marketing is relevant to measuring the 180-day period. As the district court explained (App., *infra*, 75a), Congress's use of "licensed" reflects the fact that, by the time the biosimilar product is commercially marketed, it will be "licensed under subsection (k)." *See* 42 U.S.C. § 262(a)(1)(A); *see also* App., *infra*, 75a ("'Before' modifies 'first commercial marketing'; 'licensed' refers only to 'biological product'—not the appropriate time for notice.").

The provision's use of "licensed under subsection (k)" also is consistent with Congress's use of the phrase elsewhere simply to distinguish between the two different ways that a biologic product can be licensed: under subsection (k) as opposed to under subsection (a). For example, the BPCIA provides that a biologic cannot be marketed unless "a biologics license under this subsection [i.e., subsection (a)] or subsection (k) is in effect for the biological product." 42 U.S.C. § 262(a)(1)(A). The statute also defines a "reference product" as a "biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." *Id.* § 262(i)(4).

In nevertheless finding a temporal requirement buried in "licensed," the Federal Circuit ignored this Court's admonition that Congress does not "hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001). As the district court aptly observed in rejecting Amgen's argument, "[h]ad Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so." App., *infra*, 76a. If Congress had wished to preclude notice until after FDA approval, it would have said so directly.

Other textual language reinforces that the Federal Circuit's interpretation is wrong. The notice of commercial marketing provision expressly authorizes a "subsection (k) *applicant*" to provide the notice. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). The provision thus contemplates that the notifying party needs only to have requested FDA approval, not to have received it. Elsewhere in the statute, Congress refers to parties holding approved applications as "holders." *See id.* § 262(m)(3) (referring to "the holder of an approved application"). If Congress had meant to require approval before notice, it would have used consistent language here and called the notifying party "the holder of an approved application."

The Federal Circuit's interpretation of Section 262(*l*)(8)(A) also makes little sense, as it renders the "notice" pointless. The provision's purpose is to "provide *notice* to the reference product sponsor" at least 180 days before the applicant intends to market

its biosimilar, *id.* § 262(*l*)(8)(A) (emphasis added), so that the sponsor can sue on any patent claims it has not yet asserted. The Federal Circuit recognized this was the provision's purpose. *See* App., *infra*, 7a (observing that the notice "allows the [sponsor] a period of time to seek a preliminary injunction based on patents"). But that purpose is better served before approval. Indeed, there is no need for special notice after approval: FDA licensure of a biosimilar is a public act. *See, e.g.*, Press Release, FDA, *FDA Approves First Biosimilar Product Zarxio* (Mar. 6, 2015) (announcing approval of Sandoz's application for filgrastim).[8]

The Federal Circuit thought that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." App., *infra*, 21a. Whatever the merits of that policy-based rationale, there is no basis for it in the text of the statute. The BPCIA's amendments to the patent laws establish a crystallized patent dispute upon the filing of a biosimilar application with the FDA. 42 U.S.C. § 262(*l*)(2)(A). In the artificial infringement actions created by the statute, it is the application that "circumscribes and dominates the assessment of potential infringement." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014). But if, as the Federal Circuit believed, notice had to await licensure,

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[8] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.

there would be no need for the artificial infringement suits that the notice allows. After licensure, the alleged actual infringement would be sufficiently imminent that the sponsor or applicant could simply file a declaratory judgment suit and seek a preliminary injunction under the ordinary infringement provisions of 35 U.S.C. § 271(a) and/or (g). *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570-71 (Fed. Cir. 1997).

2. *The Federal Circuit's ruling disrupts the careful balance struck by Congress by delaying the launch of every biosimilar product by six months*

a. The Federal Circuit's ruling disrupts the careful balance struck by Congress. In the BPCIA, Congress sought to facilitate prompt access to cost-saving biosimilars while promoting innovation in biologics. BPCIA § 7001(b), 124 Stat. at 804 (reproduced at App., *infra*, 87a). To speed competing biosimilars to market, Congress allowed the FDA to approve biosimilar products by relying in part on previous approvals of reference products. App., *infra*, 5a-6a; 42 U.S.C. § 262(i)(2), (k). In exchange, Congress granted reference product sponsors up to 12 years of exclusivity from competition from biosimilars—regardless of whether the sponsor has any valid patent claims.

Specifically, in a section titled "Exclusivity for reference product," Congress provided that the FDA's

"[a]pproval of [a biosimilar] application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed." 42 U.S.C. § 262(k)(7)(A). Under the clear terms of this provision, once the expressly granted exclusivity period has run, the FDA's approval is "made effective," and the biosimilar applicant should be able to market immediately, absent the successful assertion by the sponsor of any valid patent claims.

Not so under the Federal Circuit's ruling: the applicant must first obtain approval from the FDA, then give notice to the sponsor (of the self-evident fact) that it intends to market its now-approved biosimilar, and finally wait 180 days before marketing. App., *infra*, 20a. As Judge Chen explained in dissent, the majority's reading of the notice of commercial marketing provision gives the sponsor an "extra-statutory exclusivity windfall"—"a 180-day injunction beyond the express twelve-year statutory exclusivity period." App., *infra*, 43a-44a (Chen, J., dissenting). But as Judge Chen observed, "[i]f Congress intended to create a 180-day automatic stay it understood how to do so." App., *infra*, 52a-53a (Chen, J., dissenting). Indeed, Congress expressly extended the exclusivity period to "12 years and 6 months rather than 12 years" for sponsors that successfully complete pediatric studies. 42 U.S.C. § 262(m)(2)(A).

Congress also "could have tied FDA approval to the notice provision" by providing that FDA approval cannot be effective until 180 days after notice is

given. App., *infra*, 53a (Chen, J., dissenting). Congress did not do so. Instead, it expressly directed that the approval be "made effective" upon expiration of the statutorily defined exclusivity period. 42 U.S.C. § 262(k)(7)(A). Nevertheless, the Federal Circuit radically transformed this mere notice provision into an automatic six-month bar against the marketing of an already-approved biosimilar. In doing so, it effectively stripped the FDA of its authority to make its biosimilar approvals "effective" at the end of the statutorily prescribed exclusivity period. *Ibid.*

The Federal Circuit attempted to downplay the significance of its holding by suggesting that the extra 180 days of exclusivity "will not likely be the usual case, as [applications] will often be filed during the 12-year exclusivity period for other products." App., *infra*, 22a. That does not follow. The Federal Circuit's holding hinges on the "licensed" product language in subsection (*l*)(8)(A). Until the 12 years of statutory exclusivity has run, the biosimilar will not be "licensed." *See* 42 U.S.C. § 262(k)(7)(A); Draft Guidance, FDA, *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* 2 (Aug. 2014).[9] Under the Federal Circuit's decision, only at that point can the applicant provide an effective notice of commercial marketing. App., *infra*, 20a. As a result,

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[9] http://www.fda.gov/downloads/drugs/guidancecompliance regulatoryinformation/guidances/ucm407844.pdf.

if the Federal Circuit's decision is left standing, *all* biosimilars will be delayed by 180 days.

b. While adding six months of exclusivity found nowhere in the statute, the Federal Circuit's ruling also frustrates the BPCIA's early patent resolution regime. Congress sought to have patent disputes resolved early—preferably before approval—so that biosimilars can be available to patients as soon as possible. To that end, Congress created new artificial infringement actions to allow patent suits to be brought before any actual infringement has occurred, long before FDA approval. 35 U.S.C. § 271(e)(2)(C).

But the Federal Circuit's ruling will mean that, in *every* situation where the parties participate in the patent exchange process, any not yet litigated patents cannot even *begin* to be litigated until after FDA approval. That is because, when the applicant and the sponsor are engaging (or have engaged) in the patent exchange process, only agreed-upon patents may be litigated before the notice of commercial marketing is given. Any other patents in dispute are subject to a stay on artificial infringement declaratory judgment suits. The notice lifts that stay. 42 U.S.C. § 262(*l*)(9)(A) (lifting stay on patents described in § 262(*l*)(8)(B)(i) and (ii)). Provision of the notice also allows the sponsor (if and when it chooses) to ask for preliminary injunctive relief. *Id.* § 262(*l*)(8)(B). If, as the Federal Circuit held, notice cannot be given until after FDA approval, any remaining litigation cannot even be initiated until after approval. Nothing in the statute supports that result, which is

entirely inconsistent with a statute structured to maximize the chance that any patent disputes will be resolved *before* FDA approval.

3. The Federal Circuit erroneously divorced the notice of commercial marketing provision from the patent resolution scheme and created an extra-textual injunctive remedy to enforce it

a. The Federal Circuit's incorrect reading of the notice of commercial marketing provision also caused it to transform the notice provision into a stand-alone requirement unconnected from the BPCIA's patent resolution provisions and to distort the BPCIA's patent-oriented remedial scheme. After concluding that the 180-day notice could not be given until after FDA approval, the majority disregarded the remedies provided by the BPCIA and instead created its own extra-textual remedy to enforce its interpretation: a private right of action for an automatic injunction. That judicially created injunction bars the marketing of the already approved biosimilar until 180 days after the post-approval notice—without regard to whether the sponsor could show any valid patent rights or any irreparable harm. That ruling conflicts with the BPCIA and this Court's precedents tightly circumscribing courts' ability to infer rights of action not expressly created by Congress.

This Court has made clear that courts are not free to fashion their own remedies. *See Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001). "Like substantive federal law itself, private rights of action to

enforce federal law must be created by Congress." *Id.* at 286. "The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy." *Ibid.* "Without it, a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-87.

As this Court has emphasized, where "a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. Nat'l Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989). Other Circuits follow that rule: "to imply injunctive authority" in a statute that does not expressly provide it "would exceed what was contemplated by the executive and legislative branches in enacting" the statute and "arrogate to [courts] powers rightfully retained by those two branches of government." *Colorado v. Idarado Mining Co.*, 916 F.2d 1486, 1497-98 (10th Cir. 1990); *see United States v. EME Homer City Generation, L.P.*, 727 F.3d 274, 291-96 (3d Cir. 2013); *Wheeling-Pittsburgh Steel Corp. v. Mitsui & Co.*, 221 F.3d 924 (6th Cir. 2000).

In conflict with those decisions, the Federal Circuit fashioned an injunctive remedy not contemplated by the statute and layered it on top of the remedies the statute does provide. Despite affirming dismissal of the only causes of action on appeal (two state law claims) (App., *infra*, 29a), the majority created a private right of action for an automatic

injunction to specifically enforce its reading of the notice of commercial marketing provision. App., *infra*, 25a-26a, 31a. But the BPCIA provides neither that right nor that remedy.

With the exception of the confidentiality provision—which is not applicable here—Congress did not make the provisions in Section 262(*l*) specifically enforceable. In other words, it created no cause of action for either the applicant or the sponsor to obtain an injunction to compel the other party to comply with any of the provisions in that subsection. In contrast, Congress expressly made the confidentiality provision enforceable by an injunction—and that provision proves that Congress knew how to provide an injunctive remedy when it wished to do so. *See* 42 U.S.C. § 262(*l*)(1)(H); *see also Touche Ross & Co. v. Redington*, 442 U.S. 560, 571-72 (1979) (where Congress provides a particular type of remedy in one portion of a statute but not another, that choice must be given effect).

Instead of providing for judicial enforcement of subsection (*l*)'s provisions via injunctions, the BPCIA provides patent-based remedies. As Judge Chen correctly observed, "Entitled 'Patents,' § 262(*l*) of the BPCIA concerns one thing: patent litigation." App., *infra*, at 45a (Chen, J., dissenting). The actions or inactions of the applicant and sponsor under the Section 262(*l*) provisions all lead to the same result: a possible pre-approval artificial infringement suit. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (9)(A)-(B). Moreover, the statute expressly provides

that the patent-based remedies "are the *only remedies* which may be granted by a court" for the artificial acts of infringement created by the BPCIA. 35 U.S.C. § 271(e)(4) (emphasis added); *see ibid.* (exception only for attorneys' fees). The BPCIA's express injunctive remedies against marketing therefore all require a showing of possible infringement of a valid patent, as well as the traditional factors for an injunction. *Id.* § 271(e)(2)(C), (4), (6); *see eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006).

As particularly relevant here, and consistent with the BPCIA's overall patent-based remedial approach, the remedy Congress provided for the failure to provide the notice of commercial marketing under subsection (*l*)(8)(A) is the ability to bring an artificial infringement suit. Specifically, when an applicant engages in the patent exchange process, yet does not provide notice of commercial marketing: "the reference product sponsor, but not the subsection (k) applicant, may bring" an action for a "declaration of infringement, validity, or enforceability" with respect to certain patents identified earlier in the patent exchange process. 42 U.S.C. § 262(*l*)(9)(B) (cross-referencing, *inter alia*, 42 U.S.C. § 262(*l*)(8)(A)).

Although the majority acknowledged that express remedy, it brushed it aside, concluding "it does not apply in this case" because Sandoz did not engage in the patent exchange process. App., *infra*, 25a. But as Judge Chen explained in dissent, the notice provision is not a stand-alone requirement; "it is part and parcel to, and contingent upon, the preceding steps in

the (*l*)(2)-(*l*)(8) litigation management regime." App., *infra*, 50a (Chen, J., dissenting). When there has been no initiation of the patent exchange process, "compliance with (*l*)(8)(A) [is] unnecessary." App., *infra*, 52a (Chen, J., dissenting). Moreover, in such a circumstance, a sponsor "does not need the remedy in (*l*)(9)(B) because (*l*)(9)(C) and § 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action," as Amgen has done here. App., *infra*, 51a (Chen, J., dissenting). "[T]he absence of such a remedial provision in (*l*)(9)(B) *confirms* that Congress deemed any additional remedy to be unnecessary." *Ibid.* The sponsor already "possesses the statutory right to seek a preliminary injunction for any of its patents." *Ibid.*

Even where parties have engaged in the patent exchange process, the Federal Circuit's decision in this case has led to extra-textual injunctive relief. At least one district court applying the decision below already has enjoined a biosimilar from marketing until 180 days after it notifies the sponsor of FDA approval, even though the applicant provided the sponsor its application under subsection (*l*)(2). *See Amgen Inc. v. Apotex Inc.*, No. 15-61631, slip op. at 2-8 (S.D. Fla. Dec. 9, 2015), appeal docketed, No. 16-1308 (Fed. Cir. Dec. 11, 2015).

In any event, the majority's dissatisfaction with the remedies afforded by Congress did not give it license to fashion its own. That exercise in judicial creativity directly contravenes this Court's precedents. *See, e.g.*, *Sandoval*, 532 U.S. at 286-87;

Karahalios, 489 U.S. at 533. Unless reviewed and reversed, that ruling will provide (and already is providing) an automatic 180-day post-approval injunction to every sponsor against every biosimilar product, even where the sponsor has no valid patent claims.

Finally, the injunction granted by the Federal Circuit conflicted with this Court's precedent in an additional way. The majority enjoined Sandoz without regard to traditional equitable factors, despite the district court's undisturbed findings that Amgen would suffer no irreparable harm. *See* App., *infra*, 82a-83a; D. Ct. Dkt. No. 129. That approach conflicts with this Court's decision in *eBay*, which emphasized that the Court "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination" of a statutory violation. 547 U.S. at 392-93.

b. Although Sandoz has now launched its biosimilar product, a live controversy remains concerning the notice of commercial marketing provision. This issue fits within the established exception to mootness for disputes capable of repetition, yet evading review. *See FEC v. Wis. Right to Life, Inc.*, 551 U.S. 449, 462-64 (2007). Sandoz will be a repeat biosimilar applicant; Sandoz is the global market leader for biosimilars and has a pipeline of biosimilars across various stages of development, including five programs that are in late-stage clinical trials or for which an FDA application already has

been submitted.[10] Sandoz therefore has a "reasonable expectation" that it will again be subject to the notice of commercial marketing provision. *FEC*, 551 U.S. at 463. When that happens, the 180-day period will again be too short for the issue to be "fully litigated prior to cessation or expiration" in a future case. *Id.* at 462 (citation omitted). This Court's immediate review is needed now.

B. This Court's Review Is Urgently Needed Because The Federal Circuit's Ruling Is Delaying The Availability Of All Biosimilars And Will Continue To Do So Until This Court Corrects The Circuit's Interpretation

If the Federal Circuit's incorrect ruling is not reversed, patients will have to wait six more months than Congress intended for *every* biosimilar—even though the FDA already has approved it and even if the sponsor has no valid patent rights to enforce or already has had the opportunity to assert any patent claims. As the Biosimilars Council explained in its amicus brief supporting en banc review, the Federal Circuit's "automatic, extra-statutory delay, if left uncorrected, would broadly undercut Congress's goal of greater competition in biologics markets and dramatically reduce savings to the U.S. healthcare system from biosimilars." CAFC Dkt. No. 139 at 2. This is an issue of critical importance to patients, the

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[10] Sandoz: Several Biosimilars in Late-Stage Clinical Trials, http://www.sandoz-biosimilars.com/en/clinicaltrials/sandoz-clinical-trials.shtml.

pharmaceutical industry, and purchasers, including taxpayers (who bear the cost of biologics through Medicare and Medicaid). Given the importance of the public and private interests at stake, this Court's immediate review is warranted.

In 2013, biologics accounted for approximately $80 billion in spending in the United States—approximately 25% of all pharmaceutical spending. FTC, *Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition*, 78 Fed. Reg. 68,840, 68,841 (Nov. 15, 2013).[11] Biologics are "among the most important pharmaceutical products in the United States," and they "comprise the fastest growing sector within pharmaceuticals." *Id.* at 68,840. As Mylan explained in its amicus brief supporting rehearing en banc, biologics cost on average $45 per patient per day (compared with $2 per day for traditional, chemically synthesized drugs). CAFC Dkt. No. 150 at 10. The cost of biologics regularly runs into the tens or hundreds of thousands of dollars per patient per year. Robert J. Shapiro, et al., *The Potential American Market for Generic Biological Treatments and the Associated Cost Savings* 4 (Feb. 2008);[12] *see also* CBO, Pub. No. 4043, *Effects of Using Generic Drugs on Medicare's Drug Spending* 20 (Sept. 2010) ("[Biologic]

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[11] https://www.ftc.gov/sites/default/files/documents/federal_register_notices/2013/11/131115biologicsfrn.pdf.

[12] http://www.sonecon.com/docs/studies/0208_GenericBiologicsStudy.pdf.

drugs can be particularly expensive, with prices reaching tens of thousands of dollars per patient each year.").[13]

Congress enacted the BPCIA to tackle these enormous costs by speeding biosimilars to market, while still preserving incentives for innovation. As the FDA Commissioner explained, the introduction of biosimilars would "increase competition and create substantial savings for patients, healthcare providers, and insurers." Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for Fiscal Year 2014, Hearings Before a Subcomm. of the Comm. on Appropriations on H.R. 2410/S. 1244, 113th Cong. 9 (2013) (statements of Dr. Margaret A. Hamburg). The CBO estimated that efficient introduction of biosimilars "would reduce total expenditures on biologics in the United States * * * by about $25 billion over the 2009-2018 period." CBO Cost Estimate, *supra*, at 1.

These enormous savings would result from price competition. The CBO estimates "that prices for biosimilars would ultimately be about 40 percent lower than prices of the original drugs * * * ." CBO, Pub. No. 4043, *supra*, at 21. And, according to the Congressional Research Service ("CRS"), the price of the reference product is expected to decrease by as much as 47% within five years of the launch of a

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[13] https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/09-15-prescriptiondrugs.pdf.

competing biosimilar. CRS, John R. Thomas, *Follow-On Biologics: The Law and Intellectual Property Issues*, R41483, at 17-18 (2014).[14]

An FTC report concluded that this price competition is "likely to lead to an expanded market and greater consumer access," as more patients can afford the lower-priced drugs. *See* FTC Report, *supra*, at 23. Patients taking biologics often have enormous out-of-pocket costs because insurance plans typically treat biologics as "specialty drugs," with coinsurance rates of 20% to 35%. Andrew W. Mulcahy, Zachary Predmore & Soeren Mattke, RAND Corp., *The Cost Savings Potential of Biosimilar Drugs in the United States* 11 (2014).[15]

These savings will benefit the federal government as well. The CBO estimated that the BPCIA would save the federal government $7 billion in reduced healthcare spending from 2010 to 2019. Elmendorf Letter, *supra*, at Table 5 at 10. Indeed, the BPCIA's savings were among those on which the CBO based its conclusion that the Affordable Care Act would reduce the federal budget deficit. *See id.* at 2.

Congress's goals will be frustrated unless and until this Court intervenes. Despite Judge Chen's forceful dissent, the Federal Circuit refused to rehear this issue en banc. Its fractured panel decision thus

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[14] https://www.fas.org/sgp/crs/misc/R41483.pdf.

[15] https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

will bind subsequent panels of the Federal Circuit, all district courts in the country, and the pharmaceutical industry. Indeed, as noted, a district court in Florida already has applied the decision in this case to enjoin the marketing of a different biosimilar, the cancer drug pegfilgrastim. *Amgen*, No. 15-61631, slip op. at 2-8; *see supra* p. 35. Similar injunctions are being sought in district courts in Massachusetts and Delaware as to two additional biosimilars, the rheumatoid-arthritis drug infliximab and the anemia drug epoetin alfa. *See Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-10698 (D. Mass. Aug. 24, 2015), ECF No. 72; *Amgen Inc. v. Hospira, Inc.*, No. 15-839 (D. Del. Nov. 6, 2015), ECF No. 11. Epoetin alfa has accounted for the single highest annual drug expenditure by Medicare Part B. Testimony of James Cosgrove, Director, Health Care, GAO, before the House Subcommittee on Health, Committee on Energy and Commerce, at 5 (June 28, 2013).[16]

For all these reasons, this Court's review is urgently needed. The Federal Circuit's decision is now delaying *every* patient's access to *all* biosimilars for at least 180 days after FDA approval. That situation should not be allowed to continue without this Court's plenary review.

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[16] http://www.gao.gov/assets/660/655608.pdf.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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FEBRUARY 16, 2016

APPENDIX A

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS, Judge Richard Seeborg.

Decided: July 21, 2015

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Before NEWMAN, LOURIE, and CHEN, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE.

Opinion concurring in part, dissenting in part filed by *Circuit Judge* NEWMAN.

Opinion dissenting in part filed by *Circuit Judge* CHEN.

LOURIE, *Circuit Judge*.

This appeal presents issues of first impression relating to the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010). Amgen Inc. and Amgen Manufacturing Ltd. (collectively, "Amgen") appeal from the decision of the United States District Court for the Northern District of California (1) dismissing Amgen's state law claims of unfair competition and conversion with prejudice because Sandoz Inc. ("Sandoz") did not violate the information-disclosure and notice-of-commercial-marketing provisions of the BPCIA, respectively codified at 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(8)(A); (2) granting judgment on the pleadings to Sandoz on its counterclaims seeking a declaratory judgment that it correctly interpreted the BPCIA; and (3) denying Amgen's motion for a preliminary injunction based on its state law claims. *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741, 2015 WL 1264756 (N.D. Cal. Mar. 19, 2015) ("*Opinion*").

For the reasons stated below, we affirm the dismissal of Amgen's state law claims of unfair competition and conversion, vacate the judgment on Sandoz's counterclaims and direct the district court to enter judgment consistent with our interpretation of the BPCIA, and remand for further proceedings consistent with this opinion.

A. Background

I.

In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the BPCIA,[1] which established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product ("reference product"). Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. § 355 et seq.). Congress established such "a biosimilar pathway balancing innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804.

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[1] Winston Churchill once described Russia as "a riddle wrapped in a mystery inside an enigma." Winston Churchill, *The Russian Enigma* (BBC radio broadcast Oct. 1, 1939), *available at* http://www.churchill-society-london.org.uk/RusnEnig.html. That is this statute. In these opinions, we do our best to unravel the riddle, solve the mystery, and comprehend the enigma.

The BPCIA has certain similarities in its goals and procedures to the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984), but it has several obvious differences. We note this as a matter of historical interest, but otherwise do not comment on those similarities and differences.

Traditionally, the Food and Drug Administration ("FDA") approves a biological product for commercial marketing by granting a biologics license under 42 U.S.C. § 262(a). An applicant filing a biologics license application ("BLA") typically provides clinical data to demonstrate the safety and efficacy of its product. In contrast, under the abbreviated pathway created by the BPCIA, codified at 42 U.S.C. § 262(k), an applicant filing an abbreviated biologics license application ("aBLA" or "subsection (k) application") instead submits information to demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved reference product, together with "publicly-available information regarding the [FDA]'s previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)-(5); *see also id.* § 262(i). The BPCIA thus permits a biosimilar applicant to rely in part on the approved license of a reference product.

To balance innovation and price competition, Congress enacted the BPCIA to provide a four-year and a twelve-year exclusivity period to a reference product, both beginning on the date of first licensure of the reference product. Specifically, a subsection (k)

application "may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a)," *id.* § 262(k)(7)(B), and approval of a subsection (k) application "may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a)," *id.* § 262(k)(7)(A). Thus, a sponsor of an approved reference product (the "reference product sponsor" or "RPS") receives up to twelve years of exclusivity against follow-on products, regardless of patent protection.

Moreover, the BPCIA established a patent-dispute-resolution regime by amending Titles 28, 35, and 42 of the United States Code. The BPCIA amended the Patent Act to create an artificial "act of infringement" and to allow infringement suits based on a biosimilar application prior to FDA approval and prior to marketing of the biological product. *See* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6). The BPCIA also established a unique and elaborate process for information exchange between the biosimilar applicant and the RPS to resolve patent disputes. *See* 42 U.S.C. § 262(*l*).

Under that process, codified at 42 U.S.C. § 262(*l*), the biosimilar applicant grants the RPS confidential access to its aBLA and the manufacturing information regarding the biosimilar product no later than 20 days after the FDA accepts its application for review. *Id.* § 262(*l*)(1)-(2). The parties then exchange lists of patents for which they believe a claim of

patent infringement could reasonably be asserted by the RPS, as well as their respective positions on infringement, validity, and enforceability of those patents. *Id.* § 262(*l*)(3). Following that exchange, which could take up to six months, the parties negotiate to formulate a list of patents ("listed patents") that would be the subject of an immediate infringement action, *id.* § 262(*l*)(4)-(5), and the RPS then sues the biosimilar applicant within 30 days, *id.* § 262(*l*)(6). That information exchange and negotiation thus contemplates an immediate infringement action brought by the RPS based only on listed patents.

Subsection 262(*l*) also provides that the applicant give notice of commercial marketing to the RPS at least 180 days prior to commercial marketing of its product licensed under subsection (k), which then allows the RPS a period of time to seek a preliminary injunction based on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents (collectively, "non-listed patents"). *Id.* § 262(*l*)(7)-(8).

Subsection 262(*l*) additionally provides, in paragraph (*l*)(9)(A), that if the applicant discloses the information "required under paragraph (2)(A)," then neither the RPS nor the applicant may bring a declaratory judgment action based on the non-listed patents prior to the date on which the RPS receives the notice of commercial marketing under paragraph (*l*)(8)(A). *Id.* § 262(*l*)(9)(A). Paragraphs (*l*)(9)(B) and

(*l*)(9)(C), however, permit the RPS, but not the applicant, to seek declaratory relief in the event that the applicant fails to comply with certain provisions of subsection (*l*). *Id.* § 262(*l*)(9)(B)-(C).

II.

Amgen has marketed filgrastim under the brand name Neupogen® ("Neupogen") since 1991. In May 2014, Sandoz filed an aBLA, seeking FDA approval of a biosimilar filgrastim product, for which Neupogen is the reference product. On July 7, 2014, Sandoz received notification from the FDA that it had accepted Sandoz's application for review.

On July 8, 2014, Sandoz notified Amgen that it had filed a biosimilar application referencing Neupogen; that it believed that the application would be approved in "Q1/2 of 2015"; and that it intended to launch its biosimilar product immediately upon FDA approval. J.A. 1472. Later in July, in response to Amgen's inquiry, Sandoz confirmed that the FDA had accepted its application for review, but Sandoz informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and that Amgen was entitled to sue Sandoz under § 262(*l*)(9)(C). J.A. 1495-96. Sandoz thus did not disclose its aBLA or its product's manufacturing information to Amgen according to § 262(*l*)(2)(A).

Subsequently, on March 6, 2015, the FDA approved Sandoz's aBLA for all approved uses of

Amgen's Neupogen. Although Sandoz has maintained that it gave an operative notice of commercial marketing in July 2014, it nevertheless gave a "further notice of commercial marketing" to Amgen on the date of FDA approval. J.A. 1774. Sandoz intended to launch its filgrastim product under the trade name Zarxio.

III.

In October 2014, Amgen sued Sandoz in the Northern District of California, asserting claims of (1) unfair competition for unlawful business practices under California Business & Professions Code § 17200 et seq. ("UCL"), based on two alleged violations of the BPCIA; (2) conversion for allegedly wrongful use of Amgen's approved license on Neupogen; and (3) infringement of Amgen's U.S. Patent 6,162,427 (the "'427 patent"), which claims a method of using filgrastim. Amgen alleged that Sandoz violated the BPCIA by failing to disclose the required information under § 262(*l*)(2)(A) and by giving a premature, ineffective, notice of commercial marketing under § 262(*l*)(8)(A) before FDA approval of its biosimilar product. Sandoz counterclaimed for a declaratory judgment that it correctly interpreted the BPCIA as permitting its actions, and that the '427 patent was invalid and not infringed.

In January 2015, the parties filed cross-motions for judgment on the pleadings on Amgen's state law claims and Sandoz's counterclaims interpreting the

BPCIA. In February 2015, Amgen also filed a motion for a preliminary injunction based solely on its state law claims to enjoin Sandoz from launching Zarxio after FDA approval. Also in February 2015, through discovery, Amgen obtained access to Sandoz's biosimilar application.

On March 19, 2015, the district court granted partial judgment on the pleadings to Sandoz on its BPCIA counterclaims to the extent that Sandoz's interpretation of the statute is consistent with the court's interpretation. Specifically, the district court concluded that: (1) the BPCIA renders permissible a subsection (k) applicant's decision not to disclose its aBLA and the manufacturing information to the RPS, subject only to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C); (2) such a decision alone does not offer a basis for the RPS to obtain injunctive relief, restitution, or damages against the applicant; and (3) the applicant may give notice of commercial marketing under § 262(*l*)(8)(A) before FDA approval. *Opinion*, 2015 WL 1264756, at *8, *11.

Based on its interpretation of the BPCIA, the district court then dismissed Amgen's unfair competition and conversion claims with prejudice because it concluded that Sandoz did not violate the BPCIA or act unlawfully. *Id.* at *8-9. The court also denied Amgen's motion for a preliminary injunction based on its state law claims, noting that Amgen "has yet to proceed on its remaining claim for patent infringement." *Id.* at *10.

On the parties' joint motion, the district court entered final judgment as to Amgen's unfair competition and conversion claims and as to Sandoz's BPCIA counterclaims under Rule 54(b) of the Federal Rules of Civil Procedure. The parties' claims and counterclaims relating to infringement, validity, and enforceability of the '427 patent remain pending at the district court.

Amgen timely appealed from the final judgment and from the denial of a preliminary injunction; we have jurisdiction under 28 U.S.C. § 1295(a)(1) and § 1292(a)(1) and (c)(1).

B. Discussion

We apply the procedural law of the regional circuit, here the Ninth Circuit, when reviewing a district court's grant of a motion for judgment on the pleadings. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1320 (Fed. Cir. 2007). The Ninth Circuit reviews the grant of judgment on the pleadings *de novo*, *Peterson v. California*, 604 F.3d 1166, 1169 (9th Cir. 2010), and "accept[s] all material allegations in the complaint as true and construe[s] them in the light most favorable to [the non-moving party]," *Turner v. Cook*, 362 F.3d 1219, 1225 (9th Cir. 2004) (third alteration in original). Issues of statutory interpretation are also reviewed *de novo*. *Qantas Airways Ltd. v. United States*, 62 F.3d 385, 387 (Fed. Cir. 1995).

Because Amgen's state law claims of unfair competition and conversion are premised on the proper interpretation of the BPCIA, we first interpret the relevant provisions of the BPCIA and then consider Amgen's state law claims in light of that interpretation.

I.

We first consider whether the district court erred in concluding that a subsection (k) applicant may elect not to disclose its aBLA and the manufacturing information under 42 U.S.C. § 262(*l*)(2)(A), subject only to the consequences set forth in § 262(*l*)(9)(C). Paragraph (*l*)(2)(A) provides that:

> Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant *shall provide* to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application . . . .

42 U.S.C. § 262(*l*)(2)(A) (emphasis added). Paragraph (*l*)(9)(C) provides that:

> If a subsection (k) applicant *fails to provide the application and information required under paragraph (2)(A)*, the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of

> Title 28, for a declaration of *infringement, validity, or enforceability of any patent* that claims the biological product or a use of the biological product.

Id. § 262(*l*)(9)(C) (emphases added). Additionally, 35 U.S.C. § 271(e)(2)(C)(ii), as amended by the BPCIA, provides that:

> It shall be an act of infringement to submit . . . if the applicant for the application *fails to provide the application and information required* under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act . . . .

35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added).[2]

Amgen argues that the language "shall provide" in paragraph (*l*)(2)(A) suggests that the information disclosure is mandatory, not merely permissible. Amgen contends that other provisions of the BPCIA refer to the information as "required" under paragraph (*l*)(2)(A) and also refer to non-disclosure as a failure to comply with the Act. Amgen argues that, by refusing to provide the required information, a subsection (k) applicant unlawfully evades the detection of process patent infringement and avoids an immediate infringement action under § 262(*l*)(6). Amgen

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[2] Section 351(*l*)(2)(A) of the Public Health Act corresponds to 42 U.S.C. § 262(*l*)(2)(A).

also argues that paragraph (*l*)(9)(C) is merely a limitation on declaratory judgment action, not a remedy, let alone the exclusive remedy, for noncompliance with paragraph (*l*)(2)(A).

Sandoz responds that the "shall" provision in paragraph (*l*)(2)(A) is only a condition precedent to engaging in the information-exchange process of paragraphs (*l*)(3) through (*l*)(6), not a mandatory requirement in all circumstances. Sandoz contends that this interpretation is consistent with the use of "shall" in paragraph (*l*)(6), which provides that the RPS "shall" file an infringement suit. Sandoz notes that this use of "shall" cannot mean that the RPS violates the statute if it chooses not to file an infringement suit. Sandoz also responds that, under the BPCIA, if a subsection (k) applicant does not disclose the information under paragraph (*l*)(2)(A), then the sponsor may file an infringement suit under paragraph (*l*)(9)(C) and obtain the information in discovery, which Amgen has done. Sandoz also contends that it did not act unlawfully by taking a path expressly contemplated by Congress and the BPCIA.

We conclude that, read in isolation, the "shall" provision in paragraph (*l*)(2)(A) appears to mean that a subsection (k) applicant is required to disclose its aBLA and manufacturing information to the RPS by the deadline specified in the statute. Indeed, the BPCIA refers to such information as "required" in other provisions. *See* 42 U.S.C. § 262(*l*)(1)(B)(i), (*l*)(9)(A), (*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Particularly, paragraph (*l*)(1)(B)(i) provides that "[w]hen" a

subsection (k) applicant submits an aBLA to the FDA, "such applicant *shall* provide . . . confidential access to the information *required* to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate" (emphases added). Thus, under the plain language of paragraph (*l*)(1)(B)(i), *when* an applicant chooses the abbreviated pathway for regulatory approval of its biosimilar product, it is required to disclose its aBLA and manufacturing information to the RPS no later than 20 days after the FDA's notification of acceptance, but not when the "when" criterion is not met.

Such a reading of "shall" in paragraph (*l*)(2)(A) is supported by the use of "may" in paragraph (*l*)(2)(B), which provides that a subsection (k) applicant "may" provide additional information requested by the RPS by the statutory deadline. Paragraph (*l*)(2)'s use of "shall" in juxtaposition with "may" in the adjacent provision would appear to indicate that "shall" signals a requirement.

However, the "shall" provision in paragraph (*l*)(2)(A) cannot be read in isolation. In other provisions, the BPCIA explicitly contemplates that a subsection (k) applicant might fail to disclose the required information by the statutory deadline. It specifically sets forth the consequence for such failure: the RPS may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). Those latter provisions indicate that "shall" in paragraph (*l*)(2)(A) does not mean "must." And the BPCIA

has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A).

Under 35 U.S.C. § 271(e)(2)(C)(ii), filing a subsection (k) application and failing to disclose the required information under paragraph (*l*)(2)(A) is an artificial "act of infringement" of "a patent that could be identified" pursuant to paragraph (*l*)(3)(A)(i). 42 U.S.C. § 262(*l*)(9)(C) further provides that "[i]f a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A)," then the RPS, but not the subsection (k) applicant, may bring a declaratory judgment action on "any patent that claims the biological product or a use of the biological product."[3] As a direct consequence of failing to comply with paragraph (*l*)(2)(A), paragraph (*l*)(9)(C) bars the subsection (k) applicant

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[3] While it is true that 42 U.S.C. § 262(*l*)(9)(C) premises the declaration judgment action on "any patent that *claims the biological product or a use of the biological product*" (emphasis added), which does not appear to include process patents, 35 U.S.C. § 271(e)(2)(C)(ii) does contemplate an infringement action based on "a patent that *could be identified pursuant to [paragraph] (l)(3)(A)(i)*" (emphasis added), which does not exclude process patents. Section 271(e)(2)(C)(ii) allows the RPS to assert process patents, "if the [subsection (k)] applicant . . . fails to provide the application and information" and "the purpose of [the subsection (k)] submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a . . . biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2).

from bringing a declaratory judgment action on patents that claim the biological product or its use.

Notably, both 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A). Once the RPS brings an infringement suit under those two provisions, it can access the required information through discovery.[4]

Importantly, mandating compliance with paragraph (*l*)(2)(A) in all circumstances would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous. *Marx v. Gen. Revenue Corp.*, 568 U.S. ___, 133 S. Ct. 1166, 1178 (2013) ("[T]he canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme."); *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." (internal quotation marks omitted)).

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[4] In addition, we note the existence of a rebuttable presumption in actions alleging infringement of a process patent under 35 U.S.C. § 271(g) relating to importation of products made abroad by a patented process. *See, e.g., Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1314 (Fed. Cir. 2011) (citing 35 U.S.C. § 295).

Moreover, 35 U.S.C. § 271(e)(4) provides "the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2)" (emphasis added). Under § 271(e)(2)(C)(ii), filing a subsection (k) application and failing to provide the required information under paragraph (*l*)(2)(A) is such an act of infringement. Here, Amgen alleged that Sandoz violated the BPCIA, but the alleged violation is precisely an act of infringement under § 271(e)(2)(C)(ii), for which § 271(e)(4) provides the "only remedies."

We therefore conclude that, even though under paragraph (*l*)(2)(A), when read in isolation, a subsection (k) applicant would be required to disclose its aBLA and the manufacturing information to the RPS by the statutory deadline, we ultimately conclude that when a subsection (k) applicant fails the disclosure requirement, 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e) expressly provide the only remedies as those being based on a claim of patent infringement. Because Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its aBLA and the manufacturing information by the statutory deadline.

II.

We next consider whether the district court erred in concluding that a subsection (k) applicant may satisfy its obligation to give notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A) by doing so before the FDA licenses its product. Paragraph

(*l*)(8)(A) provides that "[t]he subsection (k) applicant *shall* provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k)." *Id.* § 262(*l*)(8)(A) (emphases added).

a.

Amgen argues that a subsection (k) applicant may give notice of commercial marketing only after it has a "biological product licensed under subsection (k)," meaning only after the FDA has licensed the biosimilar product. Amgen notes that elsewhere subsection (*l*) refers to the biosimilar product as "the biological product that is the subject of" the application, which supports its interpretation of "licensed" in paragraph (*l*)(8)(A). Amgen explains that giving notice after FDA licensure provides time for the RPS to seek a preliminary injunction and to resolve patent disputes in a timely fashion. Amgen contends that allowing the applicant to give notice before FDA licensure is irreconcilable with the statute's text and purpose.

Sandoz responds that the plain terms of the notice provision are satisfied when an applicant provides notice at least 180 days before it commercially markets its product. According to Sandoz, the word "licensed" only means that, at the time of commercial marketing, the product must be licensed, but it does not limit the timing of the notice, which can be

given before FDA licensure. Sandoz also argues that Amgen's construction of the notice provision would transform it into an automatic, additional, six-month bar against marketing of every licensed biosimilar product, which improperly extends the twelve-year exclusivity period under § 262(k)(7)(A).

We agree with Amgen that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product. The statutory language compels such an interpretation. It means that notice, to be effective under this statute, must be given only after the product is licensed by the FDA.

In subsection (*l*), only paragraph (*l*)(8)(A) refers to the product as "the biological product licensed under subsection (k)." In other provisions of subsection (*l*), the statute refers to the product as "the biological product that is the subject of" the application, even when discussing its commercial marketing. *E.g.*, 42 U.S.C. § 262(*l*)(3)(B)(ii)(I), (*l*)(3)(C); *id.* § 262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(7)(B). If Congress intended paragraph (*l*)(8)(A) to permit effective notice before the product is licensed, it would have used the "subject of" language.

While it is true that only a licensed product may be commercially marketed, it does not follow that whenever the future commercial marketing of a yet-to-be licensed product is discussed, it is the "licensed" product. It is not yet "the licensed product." Congress could have used the phrase "the biological product

that is the subject of" the application in paragraph (*l*)(8)(A), as it did in other provisions, but it did not do so. *See, e.g.*, *Russello v. United States*, 464 U.S. 16, 23 (1983).

We believe that Congress intended the notice to follow licensure, at which time the product, its therapeutic uses, and its manufacturing processes are fixed. When a subsection (k) applicant files its aBLA, it likely does not know for certain when, or if, it will obtain FDA licensure. The FDA could request changes to the product during the review process, or it could approve some but not all sought-for uses. Giving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court.

Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product. If a notice of commercial marketing could be given at any time before FDA licensure, the RPS would be left to guess the scope of the approved license and when commercial marketing would actually begin. Indeed, filing an aBLA only suggests that a subsection (k) applicant intends to

commercially market its product someday in the future.

Furthermore, requiring FDA licensure before notice of commercial marketing does not necessarily conflict with the twelve-year exclusivity period of § 262(k)(7)(A). It is true that in this case, as we decide *infra*, Amgen will have an additional 180 days of market exclusion after Sandoz's effective notice date; that is because Sandoz only filed its aBLA 23 years after Amgen obtained FDA approval of its Neupogen product. Amgen had more than an "extra" 180 days, but that is apparently the way the law, business, and the science evolved. That extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products. A statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case. Finally, it is counterintuitive to provide that notice of commercial marketing be given at a time before one knows when, or if, the product will be approved, or licensed.

We therefore conclude that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product. The district court thus erred in holding that a notice of commercial marketing under paragraph (*l*)(8)(A) may effectively be given before the biological product is licensed, and we therefore reverse its conclusion relating to its interpretation of § 262(*l*)(8)(A) and the date when Sandoz may market its product.

b.

We next consider the consequence in this case of our interpretation of paragraph (*l*)(8)(A). Paragraph (*l*)(8)(A) provides that the subsection (k) applicant "shall provide" notice of commercial marketing to the RPS no later than 180 days before commercial marketing of the licensed product. As we have concluded, an operative notice of commercial marketing can only be given after FDA licensure. Here, Sandoz's notice in July 2014, the day after the FDA accepted its application for review, was premature and ineffective. However, the FDA approved Sandoz's aBLA on March 6, 2015, and Sandoz gave a "further" notice of commercial marketing on that day. J.A. 1774. These facts are uncontested. Oral Argument at 35:33-56, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all. That notice in March 2015 thus serves as the operative and effective notice of commercial marketing in this case.

A question exists, however, concerning whether the "shall" provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is. Both paragraph (*l*)(2)(A) and (*l*)(8)(A) use the word "shall," which presumptively signals a statutory requirement. *See, e.g.*, *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Lopez v. Davis*, 531 U.S. 230, 241 (2001). As we have noted with respect to paragraph (*l*)(2)(A), however, the BPCIA explicitly contemplates that a subsection (k) applicant might fail to comply with the requirement of paragraph (*l*)(2)(A)

and further specifies the consequence for such failure in 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). Because of those explicit statutory provisions, and to avoid construing the statute so as to render them superfluous, we have interpreted the BPCIA as allowing noncompliance with paragraph (*l*)(2)(A), subject to the consequence specified in those other provisions.

In contrast, with respect to paragraph (*l*)(8)(A), we do not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with paragraph (*l*)(8)(A) here, which would be the case if Sandoz attempts to launch in disregard of the requirement of paragraph (*l*)(8)(A), as we have interpreted it. Sandoz argues that § 262(*l*)(9)(B) does specify the consequence for noncompliance with paragraph (*l*)(8)(A). Paragraph (*l*)(9)(B), entitled "[s]ubsequent failure to act by subsection (k) applicant," provides that:

> If a subsection (k) applicant *fails to complete* an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or *paragraph (8)(A)*, the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of *any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).*

42 U.S.C. § 262(*l*)(9)(B) (emphases added).

While it is true that paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A), it does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with. Indeed, the consequence specified in paragraph (*l*)(9)(B) is a declaratory judgment action brought by the RPS based on "any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7)." 42 U.S.C. § 262(*l*)(9)(B). Here, however, because Sandoz did not provide the required information to Amgen under paragraph (*l*)(2)(A), Amgen was unable to compile a patent list as described in paragraph (*l*)(3)(A) or paragraph (*l*)(7).

Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*), and Sandoz concedes as much. Oral Argument at 39:30-52, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all. Unlike the actions described in paragraphs (*l*)(3) through (*l*)(7), which all depend on, or are triggered by, the disclosure under paragraph (*l*)(2)(A), nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*). Moreover, nothing in subsection (*l*) excuses the applicant from its obligation to give notice of commercial marketing to the RPS after it has chosen not to comply with paragraph (*l*)(2)(A). The purpose of paragraph (*l*)(8)(A) is clear: requiring notice of commercial marketing be given to

allow the RPS a period of time to assess and act upon its patent rights.

We therefore conclude that, where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory. Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015.

III.

We next consider Amgen's unfair competition and conversion claims under California law. After finding that Sandoz did not violate the BPCIA, the district court dismissed Amgen's state law claims with prejudice. We affirm the dismissal based on our interpretation of the BPCIA.[5]

a.

Under Cal. Bus. & Prof. Code § 17200, "unfair competition" includes "any unlawful, unfair or fraudulent business act or practice." Amgen's unfair competition claim is based solely on the "unlawful" prong, which requires a showing that Sandoz acted unlawfully by violating another law, here, according to

[5] In its cross-motion for judgment on the pleadings, Sandoz did not argue preemption as a defense to Amgen's state law claims, and thus the district court did not consider that issue. We therefore do not address preemption in this appeal.

Amgen, the BPCIA. *Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152, 1168 (9th Cir. 2012); *see also Farmers Ins. Exch. v. Superior Court*, 826 P.2d 730, 734 (Cal. 1992). Under California law, UCL remedies are not available when the underlying law expressly provides that the remedies in that law are exclusive. *See* Cal. Bus. & Prof. Code § 17205; *Loeffler v. Target Corp.*, 324 P.3d 50, 76 (Cal. 2014).

As one basis of its unfair competition claim, Amgen alleges that Sandoz violated the BPCIA by failing to comply with § 262(*l*)(2)(A). As we have concluded, Sandoz did not violate the BPCIA by not disclosing its aBLA and the manufacturing information according to § 262(*l*)(2)(A). Sandoz took a path expressly contemplated by 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii), and 35 U.S.C. § 271(e)(4) provides "the only remedies which may be granted by a court" for the alleged violation. We therefore affirm the dismissal of Amgen's unfair competition claim based on the alleged violation of § 262(*l*)(2)(A).

b.

As another basis of its unfair competition claim, Amgen also asserts that Sandoz violated the BPCIA by giving a premature, ineffective, notice of commercial marketing under § 262(*l*)(8)(A) in July 2014, before FDA approval in March 2015. As indicated, under our interpretation of the BPCIA, the July 2014 notice is ineffective, and Sandoz gave the operative notice on March 6, 2015. Thus, as we have indicated, Sandoz may not market Zarxio before 180 days from

March 6, 2015, *i.e.*, September 2, 2015. And, as indicated below, we will extend the injunction pending appeal through September 2, 2015. Amgen's appeal from the dismissal of its unfair competition claim based on the alleged violation of § 262(*l*)(8)(A) is therefore moot.

c.

We now turn to Amgen's conversion claim. To sustain a claim for conversion under California law, Amgen must demonstrate: (1) its ownership or right to possession of the property; (2) Sandoz's conversion by a wrongful act or disposition of property rights; and (3) damages. *Burlesci v. Petersen*, 80 Cal. Rptr. 2d 704, 706 (Cal. Ct. App. 1998). Amgen asserts that Sandoz wrongfully used Amgen's approved license on Neupogen by filing an aBLA referencing Neupogen but refusing to provide Amgen the benefits to which it is entitled under § 262(*l*). Sandoz responds that Amgen failed to show any "wrongful act" or to establish an exclusive ownership interest in the approved license on Neupogen to exclude Sandoz's aBLA.

We agree with Sandoz that Amgen failed to establish the requisite elements to sustain a claim of conversion under California law. As indicated, the BPCIA explicitly contemplates that a subsection (k) applicant might not disclose its aBLA and the manufacturing information by the statutory deadline, and

provides that the RPS may sue for patent infringement, which Amgen has done. Amgen thus failed to show a "wrongful act."

Moreover, the BPCIA established the abbreviated pathway for FDA approval of follow-on biological products, allowing a subsection (k) applicant to use "publicly-available information" regarding the reference product in its application.[6] 42 U.S.C. § 262(k)(2). The BPCIA also grants a 12-year exclusivity period to the RPS, during which approval of a subsection (k) application may not be made effective. *Id.* § 262(k)(7)(A). Neupogen's 12-year exclusivity period has long expired. Amgen therefore fails to show that it has an *exclusive* right to possession of its approved license on Neupogen to sustain its claim of conversion under California law.

We therefore affirm the dismissal of Amgen's unfair competition and conversion claims based on our interpretation of the relevant provisions of the BPCIA.

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[6] Amgen emphasizes in its briefs that Sandoz is wrongfully benefitting from Amgen's establishment of the safety and efficacy of filgrastim. Be that as it may, this is not the first time that Congress has allowed generic applicants to benefit from the early work of innovators. *See* Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984); *see also Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984). That was a decision that Congress was entitled to make and it did so.

IV.

Amgen argues that the district court erred in denying its motion for a preliminary injunction based on an incorrect reading of the BPCIA and an erroneous finding that Amgen failed to show irreparable harm. Sandoz responds that Amgen's appeal is moot because it sought an injunction only until the district court decided the parties' cross-motions for judgment on the pleadings, which has already occurred. Sandoz also responds that, even if not moot, the district court did not abuse its discretion in denying the motion and did not clearly err in its factual findings.

We agree with Sandoz that Amgen's appeal from the denial of a preliminary injunction is moot. In its motion for a preliminary injunction, filed in the district court after it filed its motion for judgment on the pleadings, Amgen requested a preliminary injunction "until the Court decides the parties' motions for judgment on the pleadings," and "if the Court resolves those motions in Amgen's favor, until . . . the parties have been placed in the position they would be in had Sandoz complied with the BPCIA." *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741 (N.D. Cal. Feb. 5, 2015), ECF No. 56, at 25.

On March 19, 2015, the district court rendered its decision on the parties' cross-motions for judgment on the pleadings, deciding against Amgen on the merits and dismissing Amgen's state law claims with prejudice. In the same order, the court also denied Amgen's motion for a preliminary injunction, which

was based solely on its state law claims. Because Amgen only requested a preliminary injunction until the district court decided the parties' motions for judgment on the pleadings, and the district court has resolved those motions against Amgen, Amgen's appeal from the denial of a preliminary injunction is moot. We therefore dismiss that aspect of Amgen's appeal.

V.

After the district court granted partial judgment on the pleadings in favor of Sandoz and denied Amgen's motion for a preliminary injunction, Amgen sought an injunction pending appeal, which the district court denied. Amgen then filed an emergency motion in this court for an injunction pending appeal. We granted the motion. In light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended through September 2, 2015.

C. Conclusion

For the foregoing reasons, we affirm the dismissal of Amgen's unfair competition and conversion claims, vacate the district court's judgment on Sandoz's counterclaims interpreting the BPCIA, and direct the district court to enter judgment on those counterclaims consistent with this opinion. We also remand for the district court to consider the patent

infringement claim and counterclaims relating to the '427 patent and any other patents properly brought into the district court action.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED

COSTS

Each party shall bear its own costs.

NEWMAN, *Circuit Judge*, concurring in part, dissenting in part.

The immediate issue relates to the Biosimilar Price Competition and Innovation Act (BPCIA) and certain obligations of the innovator/patentee (called the "reference product sponsor," or "Sponsor") and the subsection (k) applicant. Subsection (k) authorizes a biosimilar applicant to use the Sponsor's clinical safety and efficacy data in order to obtain FDA license approval for commercial marketing of the biosimilar product. By acting under subsection (k) the applicant need not obtain its own clinical data for its biosimilar product, and can receive FDA licensure by showing that "the biological product is biosimilar to a reference product," 42 U.S.C. §262(k), and has the same characteristics of safety, efficacy, and purity. *Id.*

To facilitate identification of and resolution of any patent issues, the BPCIA requires the subsection (k) applicant to notify the Sponsor at two critical stages of FDA review of the subsection (k) application.

I agree with the court that notice of issuance of the FDA license is mandatory, and that this notice starts the 180-day stay of commercial marketing, in accordance with 42 U.S.C. §262(*l*)(8)(A). Thus I join Part A, Part (B)(II), and Part B(V) of the court's opinion.

However, notice of acceptance of the filing of the subsection (k) application is also mandatory, along with the accompanying documentary and information exchanges set in the BPCIA in accordance with 42 U.S.C. §262(*l*)(2)(A). I respectfully dissent from the court's holding that this activity is not required because the Sponsor might file an infringement suit in which it might learn this information though discovery.

Sandoz did not comply with either of these statutory requirements. These deliberate violations of the requirements of the BPCIA forfeit Sandoz' access to the benefits of the BPCIA.

I

Patent dispute resolution under the BPCIA has two phases. The "early phase" starts when the subsection (k) application is accepted by the FDA for review, and technical and patent information are then exchanged. The "later phase" starts when the FDA approves the biosimilar for commercial marketing. I comment only briefly on this later phase, for I agree, as the court holds, that 42 U.S.C. §262(*l*)(8) requires that this phase of inquiry and dispute resolution commences when the subsection (k) applicant notifies

the Sponsor, after the FDA license is granted. My concern is that my colleagues on this panel do not apply, to the earlier "shall provide" words, the same mandatory meaning as for subsection (*l*)(8)(A):

> §**262(*l*)(8)(A)** *Notice of commercial marketing.*—The subsection (k) applicant **shall provide notice** to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product **licensed under subsection (k).**

(Emphases added). The BPCIA explicitly states that after licensure and before commercial marketing the Sponsor may seek a preliminary injunction while the patent aspects are resolved:

> §**262(*l*)(8)(B)** *Preliminary injunction.*—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor **may seek a preliminary injunction** prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement [of any patent identified in the early stage or other defined proceedings.]

(Emphasis added). Sandoz proposed to circumvent this provision and launch its biosimilar product immediately upon its FDA licensure.

I share the court's interpretation of this statutory provision, which implements the purpose of the BPCIA "to ensure that litigation surrounding relevant patents will be resolved expeditiously and *prior to the launch* of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcommittee On Courts and Competition Policy of the House Committee On the Judiciary*, 111th Cong. 9 (July 14, 2009) (statement of Rep. Eshoo) (emphasis added). The BPCIA requires the court to give effect to the intent of Congress. *See Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990) ("To discern Congress' intent we examine the explicit statutory language and the structure and purpose of the statute.")

II

The BPCIA provides for participants' recognition of potential patent issues at an early stage, and requires that as soon as the FDA accepts the biosimilar application for review, the subsection (k) applicant *shall* notify the Sponsor, and exchanges of patent-related information *shall* commence. Details are set forth in 42 U.S.C. §262(*l*)(2). My colleagues hold that compliance with these early notice and information provisions is not mandatory. I cannot agree, for: "The word 'shall' is ordinarily the language of command." *Alabama v. Bozeman*, 533 U.S. 146, 153 (2001).

The purpose of subsection 262(*l*) is to initiate patent-related activity, to exchange relevant information, to facilitate negotiations, and to expedite any litigation. Subsection (*l*)(2)(A) requires the subsection (k) applicant to notify the Sponsor within 20 days after the FDA accepts the subsection (k) application for review, and to describe the manufacturing process:

> §**262(*l*)(2)(A)** *Subsection (k) application information.*—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant **shall provide** to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes **the process or processes used to manufacture** the biological product that is the subject of such application.

(Emphases added). Sandoz did not provide this information, although it is required, and the BPCIA provides for confidentiality:

> §**262(*l*)(1)(B)(i)** *Provision of confidential information.*—When a subsection (k) applicant submits an application under subsection (k), such applicant **shall provide** to the persons described in clause (ii), subject to the terms of this paragraph, **confidential access to the information required** to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant

> determines in its sole discretion to be appropriate.

(Emphases added).

This designated exchange of information is fundamental to the BPCIA purposes of efficient resolution of patent issues. However, my colleagues hold that compliance by the applicant is not mandatory, citing §262(*l*)(9)(C), which authorizes suit by the Sponsor if the applicant does not provide the paragraph (2)(A) information:

> **§262(*l*)(9)(C)** *Subsection (k) application not provided.*—If a **subsection (k) applicant fails to provide** the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims **the biological product or a use** of the biological product.

(Emphases added). This provision for declaratory action by the Sponsor is limited to "product" and "use" claims, and does not include manufacturing process patents, although the legislative record makes clear that for biosimilars such patents may be highly material, and were so recognized during enactment. Amgen states that its patents here at issue relate primarily to manufacture.

I cannot agree that this provision excuses compliance by the subsection (k) applicant, even when

such declaratory action is brought. Subsection (*l*)(9)(C) provides declaratory jurisdiction only for product or use claims. Absent adequate factual support in a complaint for manufacturing method claims, declaratory jurisdiction may be unsupported. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face.") (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

The balance established in the BPCIA requires the statutorily identified disclosures at the threshold, in order both to avert and to expedite litigation. This purpose pervades the legislative record, as interested persons debated which provisions would be mandatory, and which permissive. *See, e.g., Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcommittee on Courts and Competition Policy of the House Committee on the Judiciary*, 111th Cong. *passim* (2009) (debating the provisions of H.R. 1548, which provided for mandatory patent exchange, and H.R. 1427, which provided for discretionary patent exchange). *Compare also* S. 623, 110th Cong. § (3)(a)(2)(k)(17)(E) (2007) ("nothing in this paragraph requires an applicant or prospective applicant to invoke the [patent notification and exchange] procedures set forth in this paragraph") *with* S. 1695, 110th Cong. § (2)(a)(2)(*l*)(2)(A) (2007) (the subsection (k) applicant "shall provide" application and manufacturing information). *See Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001) ("We

ordinarily will not assume that Congress intended 'to enact language that it has earlier discarded in favor of other language.'" (citations omitted)).

The BPCIA as enacted leaves no uncertainty as to which of its provisions are mandatory and which are permissive. For example, immediately after the **"shall"** provision of subsection *(l)*(2)(A), *ante*, subsection (*l*)(2)(B) states that a subsection (k) applicant

> **may** provide to the reference product sponsor **additional** information requested by or on behalf of the reference product sponsor.

(Emphases added). "[W]hen the same Rule uses both 'may' and 'shall', the normal inference is that each is used in its usual sense—the one act being permissive, the other mandatory." *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947).

In *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359-60 (1895), the Court stated that when Congress uses the "special contradistinction" of "shall" and "may," no "liberty can be taken with the plain words of the statute." As reiterated in *Sebelius v. Cloer*, 133 S. Ct. 1886, 1894 (2013), "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (alteration and internal quotation marks omitted). The BPCIA gestated during more than four years of study and debate. The record contains frequent reference to the experience of the

Hatch-Waxman Act, as the BPCIA departed from that Act in seeking to "balance innovation and consumer interests" in the new and promising scientific era of biosimilars. BPCIA, Pub. L. No. 111-148, §7001(b), 124 Stat. 119, 804 (2010). Fidelity to that balance is the judicial obligation.

The details enacted and included in the BPCIA demonstrate the rigor of the statute and its compromises. The BPCIA requires judicial implementation that conforms to "the design of the statute as a whole and to its object and policy." *Crandon v. United States*, 494 U.S. 152, 158 (1990). Subsection (k) and subsection (*l*) are components of an integrated framework; to enjoy the benefits of subsection (k), the biosimilar applicant is obligated to comply with subsection (*l*). Even on the district court's (and my colleagues') misplaced theory that subsection (*l*)(9)(C) excuses compliance with subsection (*l*)(2)(A), this would extend only to product and use claims, it does not excuse compliance as to manufacturing and process claims.

The BPCIA reflects an explicit balance of obligations and benefits. When a beneficiary of the statute withholds compliance with provisions enacted to benefit others, the withholder violates that balance. The consequences of the majority's ruling are significant, for the structure of the BPCIA requires that the subsection (k) applicant comply with the information

exchange provisions, as a threshold to resolution of the Sponsor's patent rights.[1]

Subsection (*l*)(9) provides jurisdiction in the district court when a subsection (k) applicant fails to comply with subsection (*l*), but it does not ratify non-compliance. While "a party may waive any provision, either of a contract or of a statute, intended for his benefit," *United States v. Mezzanatto*, 513 U.S. 196, 201 (1995), the party cannot waive or disregard a provision that benefits those in an adverse position. The provisions of 35 U.S.C. §262(*l*)(9) function as a continuing prohibition on a party who fails to comply with some aspect of the patent exchange provisions. That is, subsection (*l*)(9)(C) prevents a non-compliant party from obtaining relief through a declaratory judgment action, while that prohibition is lifted as to the aggrieved party. Subsection (*l*)(9)(C) states that a "reference product sponsor, but not the subsection (k) applicant, may bring" a declaratory judgment action "for a declaration of infringement, validity, or enforceability for any patent that claims the biological

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[1] The record recites the benefits of subsection (k) for biosimilar applicants. A study for the Congressional Research Service cites a Tufts report that found in 2006 the "average cost to develop a new biotechnology product is $1.2 billion." *Follow-On Biologics: The Law and Intellectual Property Issues, CRS Report for Congress*, Professor John Thomas, January 15, 1014, *passim*, n.32. The record explains that clinical safety and efficacy studies constitute the major portion of this development cost, and that subsection (k) authorizes the biosimilar applicant to rely on these data that the Sponsor provided to the FDA.

product or use of the biological product" when a subsection (k) applicant fails to provide the information required under subsection (*l*)(2)(A).

35 U.S.C. § 271(e)(2)(C)(ii) similarly states that it shall be an act of infringement if the applicant fails to provide the information required under paragraph (*l*)(2)(A). However, this does not diminish the obligation set by section (*l*)(1)(B)(i) that the subsection (k) applicant "shall provide . . . confidential access to the information required to be produced pursuant to paragraph (2)." Such obligation is mandatory.

Departure from the statutory obligation, to achieve purposes that the legislation intended to curtail, should not be judicially ratified. *See Cannon v. Univ. of Chicago*, 441 U.S. 677, 690 (1979) (disregard of a statute is a wrongful act). It is not denied that Sandoz obtained the benefit of the Amgen data in filing under subsection (k). Sandoz should be required to respect its obligations, in fidelity to the statute. I respectfully dissent from the majority's failure to require compliance with the obligations of the BPCIA.

CHEN, *Circuit Judge*, dissenting-in-part.

I join the majority opinion except for Parts B.II.b and B.V. To properly interpret the BPCIA's patent litigation management process described in section 262(*l*), I agree that none of subsection (*l*)'s provisions may be read in isolation. In other words, to understand

the meaning of any one provision in § 262(*l*), one must first recognize how it interrelates with the rest of subsection (*l*) and the rest of the BPCIA. Based on this understanding, I agree that a subsection (k) applicant's failure to supply the information described in (*l*)(2) to the reference product sponsor (RPS) is not a violation of the BPCIA, because the BPCIA itself, in (*l*)(9) and § 271(e)(2)(C)(ii), provides the RPS the remedial course of action in such circumstances. Contrary to the majority, however, I view this context-based interpretation as applying with equal force to the interpretation of (*l*)(8). When reading (*l*)(8) in the context of subsection (*l*) as a whole, it becomes clear that (*l*)(8) is simply part and parcel of the integrated litigation management process contemplated in (*l*)(2)-(*l*)(7). Moreover, just as all the "shall" obligations set forth in (*l*)(3)-(*l*)(7) are contingent on the (k) applicant's performance of the first "shall" step in (*l*)(2), this is also true of the "shall" notice obligation in (*l*)(8). What this means is when, as here, the (k) applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter. In such a situation, as recognized by the majority opinion, the RPS's course of action is clearly defined in (*l*)(9) and § 271(e)(2)(C)(ii): the unfettered right to immediately pursue patent infringement litigation unconstrained by any of the timing controls or limits on the number of patents it may assert that would result from the (*l*)(2)-(*l*)(8) process. Based on this understanding, I do not view (*l*)(8)(A) as a "standalone provision" that provides, implicitly, the RPS a 180-day injunction beyond the express twelve-year statutory exclusivity

period. Because the majority opinion interprets (*l*)(8) differently, giving Amgen, the RPS, an extra-statutory exclusivity windfall, I respectfully dissent.

I

"It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989). To that end, the Supreme Court has instructed that "statutory language cannot be construed in a vacuum." *Id.*; *see also Yates v. United States*, 135 S. Ct. 1074, 1081-82 (2015) (instructing courts to interpret statutory text by reference to "the specific context in which that language is used, and the broader context of the statute as a whole." (quotation marks omitted)). In Part B.I, the majority properly recognizes that "the 'shall' provision in paragraph (*l*)(2)(A) cannot be read in isolation." Majority Op. at 12 [*supra* p. 15a]. The majority carefully examines the larger statutory context—subsection (*l*) and § 271(e)(2)(C)(ii)—and correctly concludes that "'shall' in paragraph (*l*)(2)(A) does not mean 'must.'" Majority Op. at 13 [*supra* p. 15a]. As the majority recognizes, nothing in the BPCIA grants the RPS a procedural right to *compel* the (k) applicant's compliance with (*l*)(2)(A). In Part B.II, however, the majority holds that the word "shall" in (*l*)(8)(A) carries a different meaning than it does in (*l*)(2)(A). To reach that inconsistent result, the majority takes the view that (*l*)(8)(A) should be read in a vacuum, apart

from the context and framework of subsection (*l*), including the language of (*l*)(8)(B). I respectfully disagree.

A

Entitled "Patents," § 262(*l*) of the BPCIA concerns one thing: patent litigation. Specifically, it specifies an elaborate information exchange process between the (k) applicant and the RPS that leads up to the expected patent infringement suit that comes during the pendency of a subsection (k) application. This process begins in (*l*)(2)(A) with the requirement that the (k) applicant disclose to the RPS its biosimilar application (aBLA) and manufacturing process information. Compliance with subsection (*l*)(2)(A) triggers a cascade of events contemplated by subsection (*l*), with each successive step reliant on the performance of one or more preceding steps. This intricate process includes: the exchange of patent lists that each party believes the RPS has reasonable grounds to assert against the (k) applicant, as well as the exchange of respective infringement, validity, and enforceability positions (§ 262(*l*)(3)); a process by which the parties may limit the patents in the infringement lawsuit (§ 262(*l*)(4)-(5)); a patent infringement lawsuit, filed by the RPS, limited to the patents listed in (*l*)(4) or (*l*)(5) (§ 262(*l*)(6)); a procedure for updating the RPS's previously created (*l*)(3) patent list with newly issued or licensed patents (§ 262(*l*)(7)); a requirement that the (k) applicant provide a 180-day notice ahead of commercial marketing thereby giving the RPS time to seek a preliminary

injunction on any (*l*)(3) listed patents not asserted in the limited (*l*)(6) patent infringement suit (§ 262(*l*)(8)); and authorization for the RPS to file an immediate declaratory judgment action for patent infringement if the (k) applicant fails to comply with its specified obligations recited in (*l*)(2), (*l*)(3), (*l*)(5), (*l*)(6), (*l*)(7), or (*l*)(8) (§ 262(*l*)(9)(B)-(C)). Importantly, subsection (*l*) does not relate to the FDA approval process (for that see subsection (k)). Nor is the approval process contingent on any events related to a possible patent dispute occurring in parallel with that approval process.

By enacting the provisions in subsection (*l*), Congress created a comprehensive, integrated litigation management system. These provisions also demonstrate that Congress anticipated the situation before us here, in which the (k) applicant refuses to engage in this litigation management process. Rather than forcing the (k) applicant, by court order or some other means, to engage in the subsection (*l*) process, or conditioning the (k) application's approval on the (k) applicant fulfilling the requirements set forth in subsection (*l*), Congress instead authorized the RPS in this situation to immediately file an infringement action. *See* § 262(*l*)(9) and 35 U.S.C. § 271(e)(2)(C)(ii).

Focusing on (*l*)(8), Congress accounted for the possibility (perhaps strong likelihood) of a situation in which the (k) applicant has received FDA approval and is on the verge of commercially marketing its biosimilar product but the RPS was unable to assert all of its (*l*)(3) listed patents against the (k) applicant

in the limited (*l*)(6) patent litigation. Entitled "Notice of commercial marketing and preliminary injunction," (*l*)(8), in relevant part, is set forth below:

> **8) Notice of commercial marketing and preliminary injunction**
>
> **(A)** Notice of commercial marketing
>
> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).
>
> **(B)** Preliminary injunction
>
> After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—
>
> > **(i)** included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and
> >
> > **(ii)** not included, as applicable, on—

> **(I)** the list of patents described in paragraph (4); or
>
> **(II)** the lists of patents described in paragraph (5)(B).

Subsection (*l*)(8)(A) requires the (k) applicant to give the RPS at least 180 days' notice of its intent to begin commercially marketing the biosimilar product. One of the key questions in this appeal is, "Why would Congress insert a 180-day commercial marketing notice provision in a subsection devoted to organizing patent litigation?" Paragraph (*l*)(8)(B) provides the answer. As mentioned above, the process in (*l*)(4)-(5) can result in restricting the (*l*)(6) infringement action to a subset of the RPS's patents identified in (*l*)(3). Rather than permit the (k) applicant to launch its biosimilar product while the RPS is blocked from enforcing some of its patent rights, subsection (*l*)(8)(B) addresses that problem by authorizing the RPS to seek a preliminary injunction prohibiting commercial manufacture or sale based on the patents that were excluded from the (*l*)(6) action. Thus, the entirety of (*l*)(8), including (*l*)(8)(A)'s notice provision, serves to ensure that an RPS will be able to assert all relevant patents before the (k) applicant launches its biosimilar product. Amgen confirmed this understanding of (*l*)(8)'s purpose at oral argument. Oral Argument at 20:10-20:05, *Amgen, Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all.

Given the purpose of (*l*)(8) and its express assumption that the parties have already performed the steps in (*l*)(3), and (*l*)(4)-(*l*)(5), the most logical conclusion when reading (*l*)(8) in context is that (*l*)(8)'s vitality is predicated on the performance of the preceding steps in subsection (*l*)'s litigation management process. Without first engaging in these procedures, (*l*)(8) lacks meaning. Similarly, for example, the statutory requirement in (*l*)(3) for the parties to exchange detailed positions on infringement and validity for the patents listed under (*l*)(3) no longer applies if the (k) applicant fails to comply with (*l*)(2). Paragraph (*l*)(8)'s interdependency on the preceding steps in subsection (*l*) is further reinforced by (*l*)(7)'s cross-reference to (*l*)(8). Paragraph (*l*)(7), which sets forth a process for the RPS to update its (*l*)(3) patent list with any newly issued or licensed patents, states that any such patents "shall be subject to paragraph (8)." 42 U.S.C. § 262(*l*)(7)(B). The interwoven structure of subsection (*l*) indicates that Congress viewed the procedures of (*l*)(8) as inseverable from the preceding steps in (*l*).

The majority, on the other hand, views (*l*)(8)(A) as a standalone notice provision that is not excused when the (k) applicant fails to comply with (*l*)(2).[1] Yet,

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[1] The majority states that Sandoz "concedes" that (*l*)(8)(A) is a standalone notice provision, citing to the oral argument. I understand Sandoz's position as accepting that (*l*)(8)(A) as a standalone provision is one possible interpretation. Oral Argument at 39:30-40:30, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499

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no one disputes that the requirements of (*l*)(3) through (*l*)(7) are certainly excused in such a case. I recognize that (*l*)(8)(A), unlike (*l*)(3) through (*l*)(7), is not expressly conditioned on the earlier steps. I cannot, however, read (*l*)(8)(A) in complete isolation from (*l*)(8)(B), which *does* reference, and is predicated on the performance of, (*l*)(3) and (*l*)(4)-(*l*)(5). Thus, (*l*)(8) does not serve as a standalone provision; it is part and parcel to, and contingent upon, the preceding steps in the (*l*)(2)-(*l*)(8) litigation management regime. The most persuasive reading of subsection (*l*) as a whole is that Congress provided two paths to resolve patent disputes: (1) the intricate route expressed in (*l*)(2)-(*l*)(8); and (2) the immediate, more flexible route provided in (*l*)(9), should the (k) applicant falter on any of its obligations recited in (*l*)(2)-(*l*)(8).

B

The majority is also concerned with the absence of an express consequence for noncompliance with (*l*)(8)(A) in situations in which the (k) applicant does not comply with (*l*)(2). I agree with the majority that the remedy in (*l*)(9)(B) does not provide relief in this scenario because the RPS's right to pursue additional patent litigation at this stage under (*l*)(9)(B) is contingent on using the patents that have been "included

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(Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all.

in the list described in paragraph (3)(A)." If a (k) applicant never carries out (*l*)(2), the RPS will never create an (*l*)(3) patent list. Such a failure to adhere to (*l*)(2) would defeat the RPS's opportunity to invoke (*l*)(9)(B) if the (k) applicant refuses to comply with (*l*)(8)(A)'s notice provision.

Contrary to the majority's conclusion, however, the absence of such a remedial provision in (*l*)(9)(B) *confirms* that Congress deemed any additional remedy to be unnecessary. Congress created the fallback provision of (*l*)(9)(C) for just these circumstances. An RPS does not need the remedy in (*l*)(9)(B) because (*l*)(9)(C) and § 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action when the (k) applicant fails to comply with (*l*)(2). At this point, the RPS possesses the statutory right to seek a preliminary injunction for any of its patents that "could be identified pursuant to section [262](*l*)(3)(A)(i)." 35 U.S.C. § 271(e)(2)(C)(ii). It therefore would have been superfluous for Congress to provide the RPS with authorization to initiate an additional, redundant infringement action under (*l*)(9)(B)[2] if the (k) applicant later does not

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[2] It is worth examining (*l*)(9)(B) closely for it shows how Congress understood the (*l*)(8) notice provision to be one part of the entire subsection (*l*) litigation management process. Under (*l*)(9)(B), if a (k) applicant fails to comply with any of its obligations recited in "paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), *or paragraph (8)(A)*," the RPS may immediately bring an infringement action on any patent the RPS listed in (*l*)(3). 42 U.S.C. § 262(*l*)(9)(B) (emphasis added).

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comply with (*l*)(8)(A). Not only is compliance with (*l*)(8)(A) unnecessary under such a circumstance, but no additional remedy is needed. Thus, after Sandoz failed to perform the (*l*)(2) requirement, the only relevant provision in subsection (*l*) became (*l*)(9)(C) and § 271(e)(2)(C)(ii).

C

The practical consequence of the majority's interpretation is that (*l*)(8)(A) provides an inherent right to an automatic 180-day injunction. The majority provides no basis in the statutory language to support this automatic injunction.[3] This relief is analogous to the thirty-month stay of the Hatch-Waxman Act, which provides for an automatic stay during which the FDA cannot approve the ANDA unless the patent infringement suit is resolved or the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If

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By grouping (*l*)(8)(A) with (*l*)(3), (*l*)(5), (*l*)(6), and (*l*)(7), all of which are unquestionably part of the litigation management regime, and defining the scope of any infringement action by the patents listed in (*l*)(3), Congress evidenced that (*l*)(8)(A) is *not* a provision that stands apart from the others, but is instead part of an integrated regime with each part serving a common purpose.

[3] The majority believes that (*l*)(8)(A)'s notice provision plays a necessary role, when the (k) applicant fails to comply with (*l*)(2), to provide the RPS adequate notice of the aBLA and therefore a meaningful opportunity to assert its patent rights. In my view, the majority reads too much into (*l*)(8)(A) by empowering it with an injunction right in the limited circumstance when a (k) applicant fails to comply with (*l*)(2).

Congress intended to create a 180-day automatic stay it understood how to do so. It could have tied FDA approval to the notice provision. Yet, Congress declined to link FDA approval to a single provision in subsection (*l*). At bottom, the majority's view is in tension with the defined purpose of (*l*)(8) while providing the RPS with an atextual 180-day exclusivity windfall.

Notably, nothing in the majority opinion suggests that this automatic injunction remedy would be available in cases where the applicant complied with (*l*)(2)(A) by providing its aBLA to the RPS, but later failed to provide notice under (*l*)(8)(A). In fact, the majority's opinion creates an uncomfortable result in which the language of (*l*)(8)(A) is interpreted in two different ways, based on the (k) applicant's actions. In a situation like the present case, the (k) applicant cannot refuse to provide the 180-days' notice, because under the majority's reading, (*l*)(8)(A) authorizes an automatic entitlement to a 180 day injunction. But if a (k) applicant complies with all the requirements specified in (*l*)(2)-(*l*)(7), then the (k) applicant may still refuse to comply with the 180-day notice provision. In this scenario, there would be no automatic injunction because (*l*)(9)(B) provides the RPS with the authorization to immediately file suit on any patent it listed under (*l*)(3). Thus, in one scenario, (*l*)(8)(A) provides a 180-day injunction, but in the second scenario it does not. While the result in the latter scenario comes from the plain language of the statute, not so with the former. Nothing in the statute

supports this peculiar outcome. As explained above, in my view, the better reading of (*l*)(8) is that it does not apply, just as (*l*)(3)-(*l*)(7) do not apply, when the (k) applicant fails to comply with (*l*)(2).

II

To be sure, (*l*)(8)(A) is an integral part of the procedures for managing patent litigation that arises as a result of a party filing an aBLA. Nevertheless, (*l*)(8)(A) is simply one piece of subsection (*l*)'s integrated patent dispute puzzle that ceases to matter, just like all the other pieces preceding (*l*)(8) cease to matter, once the (k) applicant fails to comply with (*l*)(2). I do not find support in the statutory language to create an automatic 180-day injunction. Just as "shall" in (*l*)(2) does not mean "must," the same is true for the "shall" provision in (*l*)(8)(A), once it is read in context with the entirety of subsection (*l*).

As the majority opinion recognizes, this case requires us to "unravel the riddle, solve the mystery, and comprehend the enigma" that is the BPCIA. Majority Op. at 3 [*supra* p. 4a] n.1. To fulfill our judicial obligation "to say what the law is," we must choose from a series of imperfect choices. In my view, the most coherent interpretation of (*l*)(8)(A) that is consistent with the rest of the BPCIA is the one I have described above. For these reasons, I respectfully dissent from the majority's holding that (*l*)(8) is a standalone provision with an inherent right to a

180-day injunction. Accordingly, I would dissolve the injunction pending appeal.

APPENDIX B

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., et al.,

Plaintiffs,

v.

SANDOZ INC., et al.,

Defendants.

Case No. 14-cv-04741-RS

ORDER ON CROSS MOTIONS FOR JUDGMENT ON THE PLEADINGS AND DENYING MOTION FOR PRELIMINARY INJUNCTION

(Filed Mar. 19, 2015)

I. INTRODUCTION

This dispute arises from conflicting interpretations of the Biologics Price Competition and Innovation Act ("BPCIA"), which established an abbreviated pathway for producers of biologic products deemed sufficiently similar to products already on the market ("biosimilars") to receive Food and Drug Administration ("FDA") license approval. *See* 42 U.S.C. § 262(k), (*l*). The BPCIA allows a drug maker who demonstrates the biosimilarity of its product to one which has already received FDA approval (the "reference product") to rely on studies and data completed by the reference product producer ("reference product sponsor"), saving years of research and millions in costs. Through its amendments to both 42 U.S.C. § 262 and 35 U.S.C. § 271, the BPCIA also enabled a process for resolving patent disputes arising from biosimilars,

whereby applicants and sponsors may participate in a series of disclosures and negotiations aimed at narrowing or eliminating the prospect of patent litigation. While engagement in the process creates a temporary safe harbor from declaratory judgment actions, a party's failure to participate permits the opposing party to commence patent litigation.

Plaintiffs Amgen, Inc. and Amgen Manufacturing, Ltd. (collectively "Amgen") have produced and marketed the biologic product filgrastim under the brand-name Neupogen since 1991. They aver that defendants Sandoz, Inc., Sandoz International GMBH, and Sandoz GMBH,[1] who in July 2014 applied to the FDA to receive biosimilar status for their filgrastim product in order to begin selling it in the United States, behaved unlawfully under 42 U.S.C. § 262 by failing to comply with its disclosure and negotiation procedures. Amgen alleges these transgressions give rise to claims under California's Unfair Competition Law ("UCL") and for conversion, as well as patent infringement as to U.S. Patent No. 6,162,427 ("'427 patent"). Sandoz counterclaims for declaratory judgment adopting its interpretation of the BPCIA and finding its conduct permissible as to Amgen's UCL and conversion claims; and for noninfringement and invalidity of the '427 patent. The parties each filed

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[1] Of the named defendants, only Sandoz, Inc. has responded to Amgen's suit thus far. Sandoz, Inc. will be referred to herein simply as "Sandoz."

cross-motions for partial judgment on the pleadings.[2] Amgen, in addition, requests a preliminary injunction to forestall Sandoz's market entry until a disposition on the merits has issued.[3]

While there is no dispute that Sandoz did not engage in 42 U.S.C. § 262's disclosure and dispute resolution process, its decision not to do so was within its rights. Amgen's motion for partial judgment on the pleadings or partial summary judgment in the alternative is, accordingly, denied, and its UCL and conversion claims are dismissed with prejudice. As the BPCIA does not bar Sandoz's counterclaims for non-infringement and invalidity of the '427 patent, these claims may advance. In addition, Amgen's motion for preliminary injunction is, accordingly, denied.

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[2] Amgen notes that, while the standards under these rules are similar, it brings its motion under both Rule 12(c) and Rule 56 to account for conflicting case law as to whether a court may rule only as to certain claims, but not others, on a motion for judgment on the pleadings.

[3] Since then, however, the parties stipulated that Sandoz would not market its product until the earlier of either a partial judgment on the pleadings in its favor, or April 10, 2015. Sandoz further agreed that, should it receive a favorable ruling before April 10, 2015, it will give Amgen five days' notice before launching its product.

II. BACKGROUND

A. Relevant Provisions of the BPCIA

The dispute presented in the pending motions exclusively concerns questions of law—specifically, of statutory interpretation, as to several provisions in 42 U.S.C. § 262 and 35 U.S.C. § 271(e), both amended in 2010 via Congress's enactment of the BPCIA. The Act's stated purpose was to establish a "biosimilars pathway balancing innovation and consumer interests." Biologics Price Competition and Innovation Act, § 7001(b), Pub. L. No. 111-148, 124 Stat 804 (2010). At issue in particular are two central provisions of 42 U.S.C. § 262: (1) paragraphs (*l*)(2)-(*l*)(6), which lay forth the disclosure and negotiation process that commences with an applicant sharing its Biologic License Application ("BLA") and manufacturing information with the reference product sponsor within twenty days of receiving notice that the FDA has accepted the application for review; and (2) paragraph (*l*)(8), requiring an applicant to give the sponsor at least 180 days' advance notice of the first commercial marketing of its biosimilar. Understanding these particular provisions requires a review of the statutory context.

Subsection (a) of 42 U.S.C. § 262 sets forth standards for FDA approval of biologic products. Among other requirements, applicants must demonstrate that their products are safe, pure, and potent. Subsection 262(k) establishes an abbreviated pathway by which a product "biosimilar" to one previously

approved under subsection (a) (a "reference product") may rely on the FDA's prior findings of safety, purity, and potency to receive approval. According to subsection (k), any entity which demonstrates its biologic product is sufficiently similar to a reference product may apply for an FDA license to market its biosimilar product. Applications must include publicly available information as to the FDA's prior determination of the reference product's safety, purity, and potency, and may include additional publicly available information. 42 U.S.C. § 262(k)(2)(A).

The FDA may not approve a biosimilarity application until twelve years after the date on which the reference product was first licensed under subsection (a); in other words, reference products are entitled to twelve years of market exclusivity. Biosimilarity applicants are precluded from even submitting applications under subsection (k) until four years after the licensing of the reference product. 42 U.S.C. § 262(k)(7)(A), (B).

Subsection 262(*l*) sets forth a process and timeline by which an applicant and reference product sponsor "shall" participate in a series of informational exchanges regarding potential disputes over patent validity and infringement. As long as both parties continue to comply with these disclosure and negotiation steps, neither may bring a declaratory action regarding patent validity, enforceability, or infringement against the other until the applicant provides notice of its upcoming first commercial marketing. 42 U.S.C. § 262(*l*)(9)(A)-(C).

The BPCIA also added to 35 U.S.C. § 271, which governs patent infringement, a provision rendering it "an act of infringement to submit" a subsection (k) application based on a patent the reference product sponsor identified (or could have identified) as infringed by the applicant's biosimilar product under subsection (*l*)'s disclosure and negotiation procedures. 35 U.S.C. § 271(e)(2)(C). In addition to enabling a reference product sponsor to initiate an infringement action for an applicant's reliance on its product, subsection 271(e) sets forth remedies for instances in which liability for infringement is found. Where the sponsor identified or could have identified the infringed patent on its initial disclosure to the applicant under 42 U.S.C. § 262(*l*)(3), injunctive relief may be granted to prevent such infringement, while damages or other monetary relief may only be awarded if there has been commercial manufacture, use, offer to sell, or sale within the United States of an infringing product. Other than attorney fees, these are "the only remedies which may be granted by a court for [infringement of such a patent]." 35 U.S.C. § 271(e)(4)(B)-(D). Where, however, the infringed patent appears on the parties' agreed-upon list of patents that should be subject to an infringement action, 42 U.S.C. § 262(*l*)(4), or their respective lists of such patents, 42 U.S.C. § 262(*l*)(5)—and the sponsor did not sue within the time frame prescribed in subsection (*l*), had its suit dismissed without prejudice, or did not prosecute its suit to judgment in good faith—the "sole and exclusive remedy" for infringement "shall be a reasonable royalty." 35 U.S.C. § 271(e)(6).

Together, 42 U.S.C. § 262(*l*) and 35 U.S.C. § 271(e) reflect an integrated scheme that provides consequences for the choice either party makes at each step of subsection (*l*)'s information exchange to carry on the process, or end it and allow patent litigation to commence. At one step in this series of tradeoffs, for example, the applicant has sixty days to respond to a list of patents the sponsor flagged in the prior step as potential grounds for an infringement suit. The applicant, according to 42 U.S.C. § 262(*l*)(3)(B)(ii), must provide the factual and legal basis for its beliefs that any patents flagged by the sponsor are invalid, unenforceable, or not infringed by its biosimilar. If the applicant does not complete this step, however, the sponsor may bring a declaratory judgment action for any patents it flagged in the prior step. 42 U.S.C. § 262(*l*)(9)(B). Conclusion of the process yields a list of patents on which a sponsor may bring suit within thirty days. 42 U.S.C. § 262(*l*)(6). Should the sponsor elect not to do so, it may collect only a reasonable royalty. 35 U.S.C. § 271(e)(6)(A). Thus, to continue the process or to terminate it confers advantages and disadvantages the parties must weigh at each step.

B. Procedural Background

Since 1991, Amgen has produced and marketed the biologic product filgrastim under the brand-name Neupogen as a result of the FDA's approval of Amgen's application for a license to market the product pursuant to BLA No. 103353. Neupogen was originally approved for decreasing the incidence of infection, as

manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever. The FDA subsequently approved additional therapeutic indications for the drug, such as aiding faster engraftment and recovery for bone marrow transplant patients.

On July 7, 2014, Sandoz received notice that the FDA had accepted for review its BLA for approval of a biosimilar filgrastim product under subsection (k). The next day, it mailed a letter to Amgen offering to share a copy of its BLA under the protection of a proposed Offer of Conditional Access; notifying Amgen that it believed it would receive FDA approval in the first or second quarter of 2015; and stating its intent to market its biosimilar product immediately thereafter. Sandoz sent Amgen a second letter on July 25 again offering conditional access to its BLA. It also asserted therein that the BPCIA entitled it to opt out of subsection (*l*)'s procedures, and that Amgen could instead procure information via an infringement action. Amgen, it appears, declined both offers to view Sandoz's biosimilarity BLA under Sandoz's proposed terms. Only after a protracted dispute did the parties, on February 9, 2015, enter a stipulated protective order providing Amgen protected access to Sandoz's BLA and related application materials. They did not engage in any further patent information exchanges.

Amgen initiated this action on October 24, 2014, asserting claims of (1) unlawful competition under Cal.

Bus. & Prof. Code § 17200 et seq. based on two alleged violations of the BPCIA; (2) conversion; and (3) infringement of Amgen's '427 patent. According to Amgen, failure to comply with subsection (*l*)'s disclosure and negotiation procedures and its interpretation of subparagraph (*l*)(8)(A)'s 180-day notice requirement each comprise an unlawful business practice actionable under the UCL. In addition, Amgen contends, Sandoz's use of Amgen's FDA license for Neupogen in its biosimilarity BLA without abiding by subsection (*l*)'s procedures rises to an act of conversion.

Alongside its answer, the following month Sandoz asserted seven counterclaims seeking declaratory judgments in favor of its interpretation of the BPCIA, as well as non-infringement and invalidity of the '427 patent. Specifically, these counterclaims are for the following declaratory judgments: (1) subsection (k) applicants may elect not to provide their applications to the reference product sponsor, subject to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C); (2) the BPCIA does not provide for injunctive relief, restitution, or damages for failure of a subsection (k) applicant to share its BLA; (3) the BPCIA sets forth exclusive consequences for failure to comply with 42 U.S.C. § 262(*l*)'s disclosure, negotiation, and notification provisions; (4) the BPCIA renders remedies under UCL and conversion claims unlawful and/or preempted; (5) a reference product sponsor does not maintain exclusive possession or control over its

biologic product license; (6) noninfringement of the '427 patent; and (7) invalidity of the '427 patent.

Amgen now moves for partial judgment on the pleadings, or partial summary judgment in the alternative, as to the two bases in the BPCIA for its UCL claim, and for declaratory judgment barring Sandoz's sixth and seventh counterclaims. Sandoz cross-moves for partial judgment on the pleadings granting declaratory judgment in favor of its first through fifth counterclaims, for dismissal with prejudice of Amgen's UCL and conversion claims, and for denial of Amgen's motion.

III. LEGAL STANDARDS

While the Federal Circuit is the court of appeal for all cases raising claims under patent law, it defers to regional circuit courts on non-patent issues. *See* 28 U.S.C. 1338(a); *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002); *Research Corp. Techs. v. Microsoft Corp.*, 536 F.3d 1247, 1255 (Fed. Cir. 2008). Ninth Circuit law therefore governs the disposition of the parties' cross-motions.

Rule 12(c) of the Federal Rules of Civil Procedure provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Such a motion, like one brought under Rule 12(b)(6), challenges the "the legal sufficiency of the opposing party's pleadings." *Qwest Communications Corp. v. City of Berkeley*, 208 F.R.D. 288, 291 (N.D. Cal. 2002). Accordingly, "a plaintiff is

not entitled to judgment on the pleadings when the answer raises issues of fact that, if proved, would defeat recovery." *General Conference Corp. of Seventh-Day Adventists v. Seventh-Day Adventist Congregational Church*, 887 F.2d 228, 230 (9th Cir. 1989). A defendant's sufficient pleading of an applicable affirmative defense likewise will defeat a plaintiff's motion. *Id.* Regardless of what facts or affirmative defenses may be raised by an answer, however, a plaintiff's motion may not be granted absent a showing that he or she "is entitled to judgment as a matter of law." *Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc.*, 896 F.2d 1542, 1550 (9th Cir. 1989).

Rule 56(a) of the Federal Rules of Civil Procedure provides that a "court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The party who seeks summary judgment bears the initial responsibility of identifying the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party satisfies this initial burden, it shifts to the non-moving party to present specific facts showing that there is a genuine issue for trial. *Celotex*, 477 U.S. at 324. "Only disputes over facts that might affect the outcome of the suit under governing law" are material. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A genuine issue exists if the non-moving party presents evidence from which a reasonable factfinder, viewing the evidence

in the light most favorable to that party, could resolve the material issue in his or her favor. *Id.* at 248-49.

IV. DISCUSSION

As noted above, this dispute hinges on the interpretation of two portions of subsection 42 U.S.C. § 262(*l*) of the BCPIA. According to Amgen, Sandoz acted unlawfully because it (1) failed to comply with subsection (*l*)'s disclosure and negotiation procedures; and (2) intends to market its biosimilar immediately upon receiving FDA approval, rather than waiting until at least 180 days thereafter. These actions, Amgen avers, constitute the predicate wrongful behavior to sustain its claims under the UCL. Sandoz also committed conversion, avers Amgen, by making use of Amgen's FDA license for Neupogen in its biosimilarity BLA.[4]

Sandoz contends its actions have comported with the letter and spirit of the BPCIA, necessitating, therefore, the denial of Amgen's motion and dismissal of its UCL and conversion claims. As the analysis

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[4] While Amgen contended at oral argument that the BPCIA enables a private right of action from which its suit against Sandoz could, alternatively, have arisen, this set of motions does not properly raise that issue and it, accordingly, will not be addressed. Amgen is left with the untenable argument that Congress intended not a self-contained statutory scheme under the BPCIA, but rather contemplated a hunt by reference product sponsors through the laws of the fifty states to find a predicate by which to litigate a claimed BPCIA violation.

below demonstrates, Sandoz's reading of the statute is the more coherent of the two, and merits granting, in part, Sandoz's motion.

The interpretation of a statute is a question of law whose answer begins with an examination of the plain meaning of the statute. *United States v. Gomez-Osorio*, 957 F.2d 636, 639 (9th Cir. 1992). Words not otherwise defined take on their ordinary, common meaning. The court must, however, read a statute's language in context and with regard to its role in the overall statutory framework, looking to legislative history as appropriate. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *United States v. Morton*, 467 U.S. 822, 828 (1984). If the statutory language is unambiguous, and the statutory scheme is coherent and consistent, that should mark the end of a court's interpretative inquiry. *Miranda v. Anchondo*, 684 F.3d 844, 849 (9th Cir. 2012).

A. BPCIA: Disclosure and Negotiation Procedures

As noted above, Sandoz elected not to supply Amgen with a copy of its BLA and manufacturing process description within twenty days from notice that the FDA had accepted its application for review,[5]

[5] Whether Amgen effectively declined access to Sandoz's BLA within these twenty days pursuant to Sandoz's July 2014 letters is a factual matter disputed by the parties, and is not at issue here.

and to engage in subsection (*l*)'s subsequent series of disclosures and negotiations regarding potential patent disputes. These acts, Amgen avers, amount to unlawful transgressions of mandatory requirements for subsection (k) applicants set forth in 42 U.S.C. § 262(*l*)(2)-(8). Indeed, these paragraphs repeatedly use the word "shall" to describe the parties' obligations under its prescribed procedures. Subparagraph (*l*)(9)(B) moreover characterizes lack of compliance as a "fail[ure] to provide the application and information required."

While such phrasing lends support to Amgen's reading, Sandoz's overall interpretation of the statute's plain language is more persuasive. While Amgen correctly notes that subsection (*l*) uses the word "may" in certain paragraphs, thereby suggesting that the use of "shall" in others implies an action is required, several countervailing factors reflect otherwise. First, that an action "shall" be taken does not imply it is mandatory in all contexts. It is fair to read subsection (*l*) to demand that, if both parties wish to take advantage of its disclosure procedures, then they "shall" follow the prescribed procedures; in other words, these procedures are "required" where the parties elect to take advantage of their benefits, and may be taken away when parties "fail."

That compliance allows an applicant to enjoy a temporary safe harbor from litigation and, potentially, to resolve or narrow patent disputes outside court proceedings, bolsters this reading. Subparagraphs (*l*) (9)(B) and (C) contemplate the scenario in

which an applicant does not comply at all with disclosure procedures, or fails to follow through after having begun the process. They allow the reference product sponsor to commence patent litigation immediately in either instance—removing (or precluding) availability to the applicant of a litigation safe harbor. Congress took the additional step in the BPCIA to amend 35 U.S.C. § 271(e) to add that an applicant's failure to disclose information regarding a potentially infringed patent under subsection (*l*)'s requirements is immediately actionable, making it clear that such a dispute is ripe for adjudication.

Such an interpretation would not be wholly without precedent; other district courts faced with a similar question have found that failure to comply with a provision containing "shall" was not unlawful, where the statute contemplated and provided for such a scenario. See *County of Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082, 1087 (D. Minn. 2013), *aff'd*, 776 F.3d 947 (8th Cir. 2014) (finding a statute stating that "[e]very conveyance of real estate shall be recorded" and that "every such conveyance not so recorded shall be void" was not mandatory because the statutory language "specifically contemplate[d] that not all conveyances will be recorded and outlines the consequence of failing to do so.")

Further, while Amgen contends persuasively that use of subsection (*l*)'s procedures can serve important public interests, including potential reduction of patent litigation and protection for innovators, nowhere does the statute evidence Congressional intent to

enhance innovators' substantive rights. In contrast to numerous other federal civil statutes which offer a claim for relief and specify remedies, here Congress did more than remain silent—it expressly directed reference product sponsors to commence patent infringement litigation in the event of an applicant's non-compliance. Even in subsection (*l*) itself, subparagraph (*l*)(8)(B) is clear in providing the remedy of a preliminary injunction for failure to give the 180-day notice required in (*l*)(8)(A). It is therefore evident that Congress intended merely to encourage use of the statute's dispute resolution process in favor of litigation, where practicable, with the carrot of a safe harbor for applicants who otherwise would remain vulnerable to suit. The statute contains no stick to force compliance in all instances, and Amgen does not identify any basis to impute one.

Indeed Sandoz's decision not to comply with subsection (*l*) reflects how the statute's overall scheme operates to promote expedient resolution of patent disputes. Compliance with the disclosure process affords an applicant many benefits: it allows the applicant to preview which patents the reference product sponsor believes are valid and infringed, assess related factual and legal support, and exercise some control over which patents are litigated and when. An applicant with a high (or unknown) risk of liability for infringement could benefit considerably from this process: it would be able to undergo the information exchange while protected by the statute's safe harbor from litigation, and if necessary, delay its product

launch to protect the investment it made in developing its biosimilar.

On the other hand, subsection (*l*) lays out a process that could take up to 230 days—just to commence patent litigation. An applicant who values expedience over risk mitigation may believe that the disclosure and negotiation process would introduce needless communications and delay. Such an applicant may have good reason to believe that no unexpired relevant patents relate to its biosimilar, and that it is likely to prevail if challenged with an infringement suit. The applicant may, in such an instance, opt to forego its ability to bring certain types of declaratory actions and receive information about potentially relevant patents from the reference product sponsor, and instead commence litigation immediately.

Perhaps confident in its limited exposure to liability and eager to resolve patent disputes so as not to face delays to market entry, Sandoz opted to invite a suit from Amgen soon after filing its BLA with the FDA.[6] Had the parties followed subsection (*l*)'s

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[6] While Amgen contends that the path chosen by Sandoz enables biosimilar producers to evade liability for patent infringement because biosimilar producers may keep reference product sponsors in the dark about their biosimilarity BLAs and plans to take their products to market, the 180-day notice requirement addressed below mitigates such concerns. With six months' advance notice of a biosimilar producer's intent to commence sales, a reference product sponsor who believes it may have an infringement claim can file suit to access the biosimilarity BLA, manufacturing process, and other relevant information via discovery—as

(Continued on following page)

disclosure and negotiation procedures, it is unlikely the present infringement action—filed in October 2014—would have even commenced until mid-March 2015, given the 230-day timeline over which subsection (*l*)'s procedures are designed to unfold. Sandoz therefore traded in the chance to narrow the scope of potential litigation with Amgen through subsection (*l*)'s steps, in exchange for the expediency of an immediate lawsuit. The BPCIA's plain language and overall statutory scheme support a reading that renders this decision entirely permissible.

B. BPCIA: One Hundred Eighty Days' Notice Prior to First Commercial Marketing

The most reasonable interpretation of paragraph (*l*)(8) of 42 U.S.C. § 262 also favors Sandoz. As noted above, this provision dictates that an applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). Upon receiving such notice, the reference product sponsor may seek a court order enjoining such market entry until a court can decide issues of patent validity or infringement. 42 U.S.C. § 262(*l*)(8)(B). It may also

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in any other typical instance of potential infringement. While Amgen may have preferred that Sandoz share this information voluntarily, the BPCIA rendered it Sandoz's choice to make.

initiate a declaratory judgment action. 42 U.S.C. § 262(*l*)(9)(B).

Amgen makes too much of the phrase quoted above from subparagraph (*l*)(8)(A). It argues that the word "licensed," a past tense verb, means an applicant may not give the required 180-day notice to the reference product sponsor until *after* the FDA has granted approval of biosimilarity—resulting in a mandatory 180-day post-FDA approval waiting period prior to biosimilar market entry. Amgen draws support for this reading from Congress's use in other paragraphs of the statute of the phrase "subject of an application under subsection (k)" to refer to biosimilars. *See, e.g.*, 42 U.S.C. § 262(i)(2). Congress employs the distinction between the two phrasings, asserts Amgen, to signal whether it intends a particular provision to refer to a biosimilar before or after it has received FDA approval. Amgen contends that the only logical conclusion, therefore, is that because (*l*)(8)(A) refers not to the "subject of an application," but rather a "licensed" product, FDA approval must be a condition precedent to valid notice.

Amgen's attempt to bolster this interpretation by referencing a prior decision of this district, *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013), has little effect. In that case, Sandoz sued to obtain a declaratory judgment that two patents were invalid, unenforceable and would not be infringed if Sandoz used, offered to sell, sold, or imported a drug product "biosimilar" to Amgen's etanercept product Enbrel. Finding for

Amgen on Article III standing grounds, the court stated merely in passing that, in addition, Sandoz could not obtain a declaratory judgment prior to filing an FDA biosimilarity application according to the procedures set forth in 42 U.S.C. § 262(*l*). While Sandoz contended that its suit complied with section 262(*l*), which permits actions for declaratory judgment once a manufacturer of a licensed biosimilar has provided notice of commercial marketing, the district court—looking only to the language of the statute itself—wrote that "as a matter of law, [Sandoz] cannot have provided a [such notice] because . . . its [biosimilar] product is not 'licensed under subsection (k).'" *Id.* The Federal Circuit affirmed the district court's ruling on standing grounds, but expressly declined to address its BPCIA interpretation, which had not been briefed for the district court and was not dispositive in its ruling. This prior case, therefore, has little persuasive authority over the present dispute.

Indeed the more persuasive interpretation accounts for the fact that FDA approval must precede market entry. It would be nonsensical for subparagraph (*l*)(8)(A) to refer to a biosimilar as the subject of a subsection (k) application because upon its "first commercial marketing" a biosimilar must, in all instances, be a "licensed" product. "Before" modifies "first commercial marketing"; "licensed" refers only to "biological product"—not the appropriate time for notice.

Even more problematic with Amgen's reading is the impact it would have on the overall statutory

scheme. Because the FDA cannot license a biosimilar until twelve years after approval of a reference product, Amgen's reading would tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A).[7] Had Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so. Moreover, Congress presumably could have been far more explicit had it intended for infringement suits to commence only once a biosimilar receives FDA approval. It was, therefore, not wrongful for Sandoz to give Amgen its 180 days' notice prior to first commercial marketing pursuant to subparagraph (*l*)(8)(A) in July 2014, in advance of receiving FDA approval.[8]

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[7] Amgen contends that because the FDA approval process may entail modifications to a biosimilar's properties or manufacturing process, allowing applicants to give 180-day notice prior to FDA approval would burden sponsors with the unfair task of having to aim infringement claims at a moving target. While this statutory construction may indeed disadvantage sponsors in some respects, such policy considerations are for Congress, not the courts, to address.

[8] In addition, had Sandoz failed to do so, it would be subject only to the consequences prescribed in 42 U.S.C. § 262(*l*)(9)(B)—an action for declaratory judgment regarding patent infringement, viability, or enforceability.

C. Amgen's State-Law Claims for Unlawful Business Practices and Conversion

Because Sandoz's actions did not violate the BPCIA, it has committed no unlawful or wrongful predicate act to sustain Amgen's claims under the UCL and for conversion. A plaintiff may proceed under the UCL on three possible theories. First, "unlawful" conduct that violates another law is independently actionable under § 17200. *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163, 180 (1999). Alternatively, a plaintiff may plead that defendants' conduct is "unfair" within the meaning of the several standards developed by the courts. *Id.* at 186-87, 83 (finding of unfairness must be "tethered to some legislatively declared policy or proof of some actual or threatened impact on competition"); *Lozano v. AT & T Wireless Servs., Inc.*, 504 F.3d 718, 736 (9th Cir. 2007) (requiring, in consumer cases, "unfairness be tied to a 'legislatively declared' policy" or that the harm to consumers outweighs the utility of the challenged conduct). Finally, a plaintiff may challenge "fraudulent" conduct by showing that "members of the public are likely to be deceived" by the challenged business acts or practices. *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009); *Daugherty v. Am. Honda Motor Co., Inc.*, 144 Cal. App. 4th 824, 838 (2006) (elements of violation of UCL for "fraudulent" business practices are distinct from common law fraud). Amgen tethers its UCL claim to only the first theory, averring that Sandoz behaved unlawfully by violating both subsection (*l*)'s disclosure and negotiation procedures and

paragraph (*l*)(8)(A)'s 180-day notice requirement. As shown above, however, Sandoz's actions are within its rights and subject only to the consequences contemplated in the BPCIA. Because Amgen has not shown that Sandoz violated any provision of law, its UCL claim fails.

Amgen further alleges that Sandoz's reliance on Amgen's FDA license for Neupogen in its subsection (k) application constitutes conversion. To sustain a claim for conversion, a plaintiff must demonstrate (1) the plaintiff's ownership or right to possession of the property; (2) the defendant's conversion by a wrongful act or disposition of property rights; and (3) damages. *Burlesci v. Petersen,* 68 Cal. App. 4th 1062 (1998).

Sandoz's "wrongful act," alleges Amgen, was making use of Amgen's FDA license for Neupogen without complying with subsection (*l*)'s disclosure and negotiation procedures. Yet the BPCIA expressly contemplates that a subsection (k) applicant will rely on the reference product's license and other publicly available safety and efficacy information about the reference product. Indeed, as Sandoz's decision to forego the benefits of subsection (*l*)'s disclosure and negotiation procedures and instead open itself up to immediate suit for patent infringement was entirely permissible under 42 U.S.C. § 262, Sandoz has committed no wrongful act. The effect of Amgen's position—that Congress intended for sponsors to resort to state laws to enforce mandatory provisions in a federal statute and collect remedies for their violation, in

addition to exacting the consequences written expressly into the legislation itself—is unworkable. Amgen therefore cannot maintain a claim for either unlawful business practices or conversion, and both claims are dismissed with prejudice pursuant to Sandoz's motion.

D. Sandoz's Counterclaims for Patent Noninfringement and Invalidity

Amgen contends that 42 U.S.C. § 262(*l*)(9)(C) bars the counterclaims for declaratory judgment of noninfringement and invalidity Sandoz alleges in response to Amgen's averment that Sandoz infringed its '427 patent. Subparagraph (*l*)(9)(C) states that where, as here, an applicant has not provided its BLA and manufacturing process information to the reference product sponsor, "the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." According to Amgen, this provision prohibits Sandoz, a subsection (k) applicant who has not provided its BLA and manufacturing process information to its sponsor, from raising its counterclaims for declaratory judgment regarding the '427 patent.

Asserting a counterclaim is not the equivalent of commencing a lawsuit. *See Alexander v. Hillman*, 296 U.S. 222, 241 (1935). The BPCIA addresses only an

applicant's ability to "bring an action," not to assert a counterclaim if placed in a position to defend against an infringement suit. Furthermore, as Sandoz's counterclaims arise from the same transaction or occurrence that is the subject of Amgen's claim—the validity and relevance of Amgen's '427 patent—they are compulsory, and would be waived if not asserted. Barring such claims in particular raises "real due process concerns." *See U.S. ex rel. Miller v. Bill Harbert Intern. Const., Inc.*, 505 F. Supp. 2d 20, 26 (D.D.C. 2007). Sandoz's sixth and seventh counterclaims regarding Amgen's '427 patent are, therefore, not barred by the BPCIA.

E. Amgen's Motion for Preliminary Injunction

Amgen has claimed it is entitled to both preliminary relief in advance of a decision on the merits, and, in the event of a decision in its favor, an injunctive remedy placing the parties where they would have stood had Sandoz fully complied with the BPCIA as Amgen interprets it. To obtain a preliminary injunction, a plaintiff must establish a likelihood of success on the merits; that he or she is likely to suffer irreparable harm in the absence of preliminary relief; that the balance of equities tips in his or her favor; and that an injunction would serve the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Federal Circuit applies this standard in reviewing the grant or denial of an injunction where the issues at play are unique to patent law. Where they are not, it applies the law of the regional

circuit (here, the Ninth Circuit). *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013). The Ninth Circuit has clarified that courts in this Circuit should evaluate the likelihood of success on a "sliding scale." *Alliance for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011) ("[T]he 'serious questions' version of the sliding scale test for preliminary injunctions remains viable after the Supreme Court's decision in *Winter*."). According to this test, "[a] preliminary injunction is appropriate when a plaintiff demonstrates . . . that serious questions going to the merits were raised and the balance of hardships tips sharply in the plaintiff's favor," provided, of course, that "plaintiffs must also satisfy the other [*Winter*] factors" including the likelihood of irreparable harm. *Id.* at 1135.

The parties disagree as to which standard is appropriate here. Yet because it cannot demonstrate serious questions as to the merits, let alone a likelihood of success, Amgen is foreclosed from injunctive relief under either formulation of the test for injunctive relief.

Indeed, the analysis above resolves in Sandoz's favor the merits as to the issues raised in the parties' cross-motions. Neither Sandoz's failure to supply its BLA and manufacturing process information within twenty days of learning the FDA had accepted its application for approval and subsequent decision to forego subsection (*l*)'s disclosure and negotiation

procedures,[9] nor its intention to proceed to market by giving 180-day in advance of FDA approval, constitutes wrongful or unlawful behavior. As Amgen has failed to show otherwise, neither Amgen's UCL claim nor its conversion claim is, therefore, viable; and it has yet to proceed on its remaining claim for patent infringement.

Amgen furthermore does not carry its burden to demonstrate that irreparable harm will result in the absence of injunctive relief. Amgen argues market entry of Sandoz's biosimilar filgrastim product will cause it irreparable harm in several respects, specifically by: (1) delaying or precluding Amgen (through its sales of biosimilar filgrastim and diversion of revenue from Amgen) from undertaking research and development for new drugs and potentially causing Amgen to lose staff and scientists; (2) diverting Amgen sales representatives' energy from selling new products to competing with Sandoz for filgrastim market share; (3) causing Amgen to drop the price of Neupogen to remain competitive; and (4) damaging Amgen's customer relationships and goodwill in the event that the Court compels Sandoz to remove its product from the market, thereby prompting Amgen to enforce the order or raise its prices to where they were prior to Sandoz's market entry.

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[9] Even were the BPCIA to render unlawful an applicant's failure to supply its BLA and manufacturing process information to the reference product sponsor within twenty days, whether Sandoz made such information available to Amgen in a timely manner is a factual dispute between the parties that need not be reached here.

Not only are such harms at best highly speculative; they are based on the as-yet unproven premise that Sandoz has infringed a valid patent belonging to Amgen. While Amgen has averred infringement of its '427 patent and argues that Sandoz's biosimilar filgrastim has the potential to infringe some four hundred more, *see* Declaration of Stuart Watt, it has not raised these contentions for a disposition at this juncture. It must, therefore, be assumed that no such infringement has occurred. As the twelve-year exclusivity period for Neupogen long ago expired, there exists no substantive bar to market entry for Sandoz's biosimilar filgrastim—and, consequently, no basis on which Amgen is entitled to injunctive relief or other remedies for disadvantages it may suffer due to market competition from Sandoz.

V. CONCLUSION

For the all of the aforementioned reasons, Amgen's motions for partial judgment on the pleadings or partial summary judgment in the alternative, and for preliminary injunction, are denied. Its claims under the UCL and for conversion are, furthermore, dismissed with prejudice.

Insofar as the above interpretation of the BPCIA is consistent with Sandoz's first through fifth counterclaims, judgment is hereby entered in Sandoz's favor. The BPCIA renders permissible a subsection (k) applicant's decision not to provide its BLA and/or manufacturing information to the reference product sponsor, subject only to the consequences set forth in

42 U.S.C. § 262(*l*)(9)(C). Such a decision alone does not offer a basis for the sponsor to obtain injunctive relief, restitution, or damages against the applicant; indeed, 42 U.S.C. § 262(*l*)(9) sets out the exclusive consequences for an applicant who elects not to provide its BLA and/or manufacturing information, or participate in any aspect of subsection (*l*)'s disclosure and negotiation process. As the BPCIA contemplates that a subsection (k) applicant will use the reference product sponsor's FDA license, and does not declare it unlawful for the applicant to do so without participating in subsection (*l*)'s disclosure and negotiation process, there exists no predicate wrongful act on which to base Amgen's conversion claim.[10] In addition, the BPCIA poses no bar to Sandoz's sixth and seventh counterclaims for patent noninfringement and invalidity as to Amgen's '427 patent.

IT IS SO ORDERED.

Dated: March 19, 2015

/s/ Richard Seeborg
RICHARD SEEBORG
United States District Judge

[10] Whether a sponsor otherwise maintains some exclusive property rights over an FDA license obtained for a biologic product is beyond the scope of this disposition.

APPENDIX C

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS, Judge Richard Seeborg.

ON PETITION FOR REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.

PER CURIAM.

ORDER

Appellants Amgen Inc. and Amgen Manufacturing Limited filed a petition for rehearing en banc. A response thereto was invited by the court and filed by Appellee Sandoz Inc. A petition for rehearing en banc was filed by Sandoz Inc., and a response was invited by the court and filed by appellants Amgen Inc. and Amgen Manufacturing Limited. The petitions for rehearing were first referred to the panel that heard the appeal, and thereafter, to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petitions for panel rehearing are denied.

The petitions for rehearing en banc are denied.

The mandate of the court will issue on October 23, 2015.

FOR THE COURT

October 16, 2015
Date

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

APPENDIX D

Public Law 111-148
111th Congress

An Act

Entitled The Patient
Protection and Affordable Care Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

* * *

TITLE VII—IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES

Subtitle A—Biologics Price Competition and Innovation

SEC. 7001. SHORT TITLE.

(a) IN GENERAL.—This subtitle may be cited as the "Biologics Price Competition and Innovation Act of 2009".

(b) SENSE OF THE SENATE.—It is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established.

SEC. 7002. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—Section 351 of the

Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting "under this subsection or subsection (k)" after "biologics license"; and

(2) by adding at the end the following:

"(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

"(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

"(2) CONTENT.—

"(A) IN GENERAL.—

"(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

"(I) the biological product is biosimilar to a reference product based upon data derived from—

"(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

"(bb) animal studies (including the assessment of toxicity); and

"(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

"(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

"(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

"(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

"(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

"(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

"(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

"(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

"(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

"(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

"(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

"(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

"(i) is biosimilar to the reference product; or

"(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

"(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

"(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

"(A) the biological product—

"(i) is biosimilar to the reference product; and

"(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

"(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

"(5) GENERAL RULES.—

"(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

"(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

"(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

"(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

"(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

"(B) 18 months after—

"(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

"(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

"(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection

(l)(6) and such litigation is still ongoing within such 42-month period; or

"(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term 'final court decision' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

"(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

"(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

"(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

"(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

"(i) a supplement for the biological product that is the reference product; or

"(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

"(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

"(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

"(8) GUIDANCE DOCUMENTS.—

"(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

"(B) PUBLIC COMMENT.—

"(i) IN GENERAL.—The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

"(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

"(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

"(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

"(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

"(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

"(E) CERTAIN PRODUCT CLASSES.—

"(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow

approval of an application for a license as provided under this subsection for such product or product class.

"(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

"(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

"(l) PATENTS.—

"(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION.—

"(A) APPLICATION OF PARAGRAPH.—Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the 'subsection (k) applicant') and the sponsor of the application for the reference product (referred to in this subsection as the 'reference product sponsor'), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

"(B) IN GENERAL.—

"(i) PROVISION OF CONFIDENTIAL INFORMATION.—When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the 'confidential information').

"(ii) RECIPIENTS OF INFORMATION.—The persons described in this clause are the following:

"(I) OUTSIDE COUNSEL.—One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the 'outside counsel'), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

"(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in

patent prosecution relevant or related to the reference product.

"(iii) PATENT OWNER ACCESS.—A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

"(C) LIMITATION ON DISCLOSURE.—No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

"(D) USE OF CONFIDENTIAL INFORMATION.—Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the

manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

"(E) OWNERSHIP OF CONFIDENTIAL INFORMATION.—The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

"(F) EFFECT OF INFRINGEMENT ACTION.—In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy

such information, it will confirm destruction in writing to the subsection (k) applicant.

"(G) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

"(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

"(H) EFFECT OF VIOLATION.—The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

"(2) SUBSECTION (k) APPLICATION INFORMATION.—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

"(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes

the process or processes used to manufacture the biological product that is the subject of such application; and

"(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

"(3) LIST AND DESCRIPTION OF PATENTS.—

"(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

"(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

"(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

"(B) LIST AND DESCRIPTION BY SUBSECTION (k) APPLICANT.—Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

"(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

"(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

"(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

"(II) a statement that the subsection (k) applicant does not intend

to begin commercial marketing of the biological product before the date that such patent expires; and

"(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

"(C) DESCRIPTION BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

"(4) PATENT RESOLUTION NEGOTIATIONS.—

"(A) IN GENERAL.—After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the

subject of an action for patent infringement under paragraph (6).

"(B) FAILURE TO REACH AGREEMENT.—If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

"(5) PATENT RESOLUTION IF NO AGREEMENT.—

"(A) NUMBER OF PATENTS.—The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

"(B) EXCHANGE OF PATENT LISTS.—

"(i) IN GENERAL.—On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

"(I) the list of patents that the subsection (k) applicant believes

should be the subject of an action for patent infringement under paragraph (6); and

"(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

"(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR.—

"(I) IN GENERAL.—Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

"(II) EXCEPTION.—If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

"(6) IMMEDIATE PATENT INFRINGEMENT ACTION.—

"(A) ACTION IF AGREEMENT ON PATENT LIST.—If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for

patent infringement with respect to each such patent.

"(B) ACTION IF NO AGREEMENT ON PATENT LIST.—If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

"(C) NOTIFICATION AND PUBLICATION OF COMPLAINT.—

"(i) NOTIFICATION TO SECRETARY.—Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

"(ii) PUBLICATION BY SECRETARY.—The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

"(7) NEWLY ISSUED OR LICENSED PATENTS.—In the case of a patent that—

"(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

"(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

"(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION.—

"(A) NOTICE OF COMMERCIAL MARKETING.—The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

"(B) PRELIMINARY INJUNCTION.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the

reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

"(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

"(ii) not included, as applicable, on—

"(I) the list of patents described in paragraph (4); or

"(II) the lists of patents described in paragraph (5)(B).

"(C) REASONABLE COOPERATION.—If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

"(9) LIMITATION ON DECLARATORY JUDGMENT ACTION.—

"(A) SUBSECTION (k) APPLICATION PROVIDED.—If a subsection (k) applicant provides the application and information required

under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

"(B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (k) APPLICANT.—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

"(C) SUBSECTION (k) APPLICATION NOT PROVIDED.—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.".

(b) DEFINITIONS.—Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—

(1) by striking "In this section, the term 'biological product' means" and inserting the following: "In this section:

"(1) The term 'biological product' means";

(2) in paragraph (1), as so designated, by inserting "protein (except any chemically synthesized polypeptide)," after "allergenic product,"; and

(3) by adding at the end the following:

"(2) The term 'biosimilar' or 'biosimilarity', in reference to a biological product that is the subject of an application under subsection (k), means—

"(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

"(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

"(3) The term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

"(4) The term 'reference product' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).".

(c) CONFORMING AMENDMENTS RELATING TO PATENTS.—

(1) PATENTS.—Section 271(e) of title 35, United States Code, is amended—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking "or" at the end;

(ii) in subparagraph (B), by adding "or" at the end; and

(iii) by inserting after subparagraph (B) the following:

"(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

"(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,"; and

(iv) in the matter following subparagraph (C) (as added by clause (iii)),

by striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product";

(B) in paragraph (4)—

(i) in subparagraph (B), by—

(I) striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product"; and

(II) striking "and" at the end;

(ii) in subparagraph (C), by—

(I) striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product"; and

(II) striking the period and inserting ", and";

(iii) by inserting after subparagraph (C) the following:

"(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet

been approved because of section 351(k)(7) of such Act."; and

(iv) in the matter following subparagraph (D) (as added by clause (iii)), by striking "and (C)" and inserting "(C), and (D)"; and

(C) by adding at the end the following:

"(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

"(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

"(ii) for which an action for infringement of the patent with respect to the biological product—

"(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

"(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

"(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a

finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

"(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.".

(2) CONFORMING AMENDMENT UNDER TITLE 28.—Section 2201(b) of title 28, United States Code, is amended by inserting before the period the following: ", or section 351 of the Public Health Service Act".

(d) CONFORMING AMENDMENTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) CONTENT AND REVIEW OF APPLICATIONS.—Section 505(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by inserting before the period at the end of the first sentence the following: "or, with respect to an applicant for approval of a biological product under section 351(k) of the Public Health Service Act, any necessary clinical study or studies".

(2) NEW ACTIVE INGREDIENT.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 355c) is amended by adding at the end the following:

"(n) NEW ACTIVE INGREDIENT.—

"(1) NON-INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is biosimilar to a reference product under section 351 of the Public Health Service Act, and that the Secretary has not determined to meet the standards described in subsection (k)(4) of such section for interchangeability with the reference product, shall be considered to have a new active ingredient under this section.

"(2) INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is interchangeable with a reference product under section 351 of the Public Health Service Act shall not be considered to have a new active ingredient under this section.".

(e) PRODUCTS PREVIOUSLY APPROVED UNDER SECTION 505.—

(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

(A) such biological product is in a product class for which a biological product in

such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act; and

(B) such application—

(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle as the "Secretary") before the date of enactment of this Act; or

(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

(4) DEEMED APPROVED UNDER SECTION 351.—An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

(5) DEFINITIONS.—For purposes of this subsection, the term "biological product" has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(f) FOLLOW-ON BIOLOGICS USER FEES.—

(1) DEVELOPMENT OF USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) IN GENERAL.—Beginning not later than October 1, 2010, the Secretary shall develop recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of biosimilar biological product applications submitted under section 351(k) of the Public Health Service Act (as added by this Act) for the first 5 fiscal years after fiscal year 2012. In developing such recommendations, the Secretary shall consult with—

(i) the Committee on Health, Education, Labor, and Pensions of the Senate;

(ii) the Committee on Energy and Commerce of the House of Representatives;

(iii) scientific and academic experts;

(iv) health care professionals;

(v) representatives of patient and consumer advocacy groups; and

(vi) the regulated industry.

(B) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(i) present the recommendations developed under subparagraph (A) to the Congressional committees specified in such subparagraph;

(ii) publish such recommendations in the Federal Register;

(iii) provide for a period of 30 days for the public to provide written comments on such recommendations;

(iv) hold a meeting at which the public may present its views on such recommendations; and

(v) after consideration of such public views and comments, revise such recommendations as necessary.

(C) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under subparagraph (B), a summary of the views and comments received under such subparagraph, and any changes made to the recommendations in response to such views and comments.

(2) ESTABLISHMENT OF USER FEE PROGRAM.—It is the sense of the Senate that, based on the recommendations transmitted to Congress by the Secretary pursuant to paragraph (1)(C), Congress

should authorize a program, effective on October 1, 2012, for the collection of user fees relating to the submission of biosimilar biological product applications under section 351(k) of the Public Health Service Act (as added by this Act).

(3) TRANSITIONAL PROVISIONS FOR USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) APPLICATION OF THE PRESCRIPTION DRUG USER FEE PROVISIONS.—Section 735(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)(B)) is amended by striking "section 351" and inserting "subsection (a) or (k) of section 351".

(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—During the period beginning on the date of enactment of this Act and ending on October 1, 2010, the Secretary shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act (as added by this Act) during such period.

(C) AUDIT.—

(i) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs

of reviewing such applications under such section 351(k). Such an audit shall compare—

(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

(II)(aa) such ratio determined under subclause (I); to

(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

(ii) ALTERATION OF USER FEE.—If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) to more appropriately account for the costs of reviewing such applications.

(iii) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State [sic]

Code, to ensure the validity of any potential variability.

(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection such sums as may be necessary for each of fiscal years 2010 through 2012.

(g) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(m) PEDIATRIC STUDIES.—

"(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (i), (j), (k), (l), (p), and (q) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

"(2) MARKET EXCLUSIVITY FOR NEW BIOLOGICAL PRODUCTS.—If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are

completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

> "(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and
>
> "(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

"(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS.—If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

"(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

"(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

"(4) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) is made later than 9 months prior to the expiration of such period.".

(2) STUDIES REGARDING PEDIATRIC RESEARCH.—

(A) PROGRAM FOR PEDIATRIC STUDY OF DRUGS.—Subsection (a)(1) of section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended by inserting ", biological products," after "including drugs".

(B) INSTITUTE OF MEDICINE STUDY.—Section 505A(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355b(p)) is amended by striking paragraphs (4) and (5) and inserting the following:

"(4) review and assess the number and importance of biological products for children that are being tested as a result of the amendments made by the Biologics Price Competition and Innovation Act of 2009 and the importance for children, health care providers, parents, and others

of labeling changes made as a result of such testing;

"(5) review and assess the number, importance, and prioritization of any biological products that are not being tested for pediatric use; and

"(6) offer recommendations for ensuring pediatric testing of biological products, including consideration of any incentives, such as those provided under this section or section 351(m) of the Public Health Service Act.".

(h) ORPHAN PRODUCTS.—If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with, such reference product may be licensed by the Secretary only after the expiration for such reference product of the later of—

(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

(2) the 12-year period described in subsection (k)(7) of such section 351.

SEC. 7003. SAVINGS.

(a) DETERMINATION.—The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle.

(b) USE.—Notwithstanding any other provision of this subtitle (or an amendment made by this subtitle), the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction.

APPENDIX E

TITLE 28—JUDICIARY AND JUDICIAL PROCEDURE

PART VI—PARTICULAR PROCEEDINGS

CHAPTER 151—DECLARATORY JUDGMENTS

§ 2201. Creation of remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act.

TITLE 35—PATENTS

PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

CHAPTER 28—INFRINGEMENT OF PATENTS

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

* * *

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or

the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the

infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of

title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section

351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

* * *

TITLE 42—THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A—PUBLIC HEALTH SERVICE

SUBCHAPTER II—GENERAL POWERS AND DUTIES

PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

SUBPART 1—BIOLOGICAL PRODUCTS

§ 262. Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c].

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility

that is the subject of the application, in accordance with subsection (c) of this section.

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505-1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(o), (p), 355-1].

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

* * *

(i) "Biological product" defined

In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

* * *

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) Additional information

An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) Evaluation by Secretary

Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) General rules

(A) One reference product per application

A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) Review

An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) Risk evaluation and mitigation strategies

The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) Exclusivity for first interchangeable biological product

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for

any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such

application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of

the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) Guidance documents

(A) In general

The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(h)] with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) Public comment

(i) In general

The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) Input regarding most valuable guidance

The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) No requirement for application consideration

The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) Requirement for product class-specific guidance

If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) Certain product classes

(i) Guidance

The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) Modification or reversal

The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) No effect on ability to deny license

Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) In-house counsel

One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) Patent owner access

A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert

the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) Ownership of confidential information

The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will

confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid,

unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the

subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a

statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7),

or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) Pediatric studies

(1) Application of certain provisions

The provisions of subsections (a), (d), (e), (f), (h), (i), (j), (k), (*l*), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(a), (d), (e), (f), (h), (i), (j), (k), (*l*), (n), (p)] shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(b), (c)].

(2) Market exclusivity for new biological products

If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product

in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(4) Exception

The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) [21 U.S.C. 355a(d)(3)] is made later than 9 months prior to the expiration of such period.

ECORD
AND
BRIEFS

Nos. 15-1039, 15-1195

FILED
MAR 10 2016
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Cross-Petitioners,

v.

SANDOZ INC.,

Cross-Respondent.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

OPENING AND RESPONSE BRIEF FOR AMGEN INC. AND AMGEN MANUFACTURING LIMITED

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QUESTIONS PRESENTED

The Biologics Price Competition and Innovation Act created a streamlined pathway for the licensure of biological products that are "biosimilar" to or "interchangeable" with a previously approved biological product, known as a reference product. 42 U.S.C. §262(k). Congress enacted a detailed procedure for the resolution of patent disputes between §262(k) applicants and reference product manufacturers, known as sponsors. *Id.* §262(*l*). The petitions present two questions concerning whether the §262(*l*) framework is mandatory or optional for applicants:

1. Is an applicant required to provide the sponsor with 180 days' notice after licensure and before it begins marketing its biosimilar product, and may a court enforce that duty by ordering the applicant not to market its product until 180 days after a post-licensure notice?

2. Is an applicant required to provide the sponsor with a copy of its biologics license application and related manufacturing information, and may a court issue an order enforcing that duty?

PARTIES TO THE PROCEEDING

The parties to the proceeding are listed in the caption. This brief refers to the respondents collectively as "Amgen."

CORPORATE DISCLOSURE STATEMENT

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation, and no publicly held corporation owns 10 percent or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with 10 percent or greater ownership in Amgen Manufacturing Limited.

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INTRODUCTION

The Biologics Price Competition and Innovation Act (BPCIA) creates a streamlined pathway for FDA licensure of biosimilars. Under that pathway, follow-on applicants can rely on data developed by biologic pioneers establishing the safety and efficacy of the approved biologic. When an applicant chooses to take advantage of the streamlined pathway, 42 U.S.C. §262(k), the statute mandates a comprehensive, two-phase procedure to ensure the fair and efficient resolution of patent disputes between the applicant and the pioneer, *id.* §262(*l*). If enforced as written, the orderly and predictable process set forth in the BPCIA achieves Congress's goal of balancing innovation and consumer interests. This case arises from Sandoz's attempt to undermine that balance by enjoying the benefits of streamlined FDA approval without following the pathway's associated patent-dispute rules.

The consolidated petitions present the Court with a fundamental dispute: Are applicants required to follow the framework Congress created, or may they choose to ignore it? Sandoz urges the latter, arguing that §262(*l*) presents not a series of commands but a series of choices. For example, where the statute says an applicant invoking the streamlined pathway "shall" provide its application and manufacturing information, 42 U.S.C. §262(*l*)(2)(A), Sandoz believes Congress simply created a choice. The same is true, in Sandoz's view, of the rest of the provisions in §262(*l*): the pioneer's duty to provide a list of relevant patents and state its intention with respect to granting a patent license; the applicant's duty to respond to that list with any noninfringement, invalidity, or unenforceability contentions or a statement that it will wait for patents to expire; the parties' duty to negotiate which patents to lit-

igate immediately; the applicant's duty to provide notice of commercial marketing; and so on. *Id.* §262(*l*)(3)-(8). Sandoz's flowchart (at 12) encapsulates its perspective. Over and over again, Congress stated that the applicant or sponsor "shall" do something. Yet over and over again, Sandoz suggests, Congress was really presenting the parties with a choice about whether or not to do what the statute says. In Sandoz's view, no court may require an applicant to take the steps that Congress provided it "shall" take.

Sandoz's construction of the BPCIA is fundamentally wrong. It rewrites the text, ignores the structure, and defies the purposes of the statute. That is particularly true with respect to the two provisions at issue here: the requirement that an applicant "shall provide to the reference product sponsor a copy of [its] application" and "information that describes the process or processes used to manufacture" its biosimilar product, 42 U.S.C. §262(*l*)(2)(A), and the requirement that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)," *id.* §262(*l*)(8)(A).

Those requirements facilitate the orderly dispute-resolution process Congress intended. By providing its application and manufacturing information, the applicant enables the sponsor to determine which of its patents may be infringed by the manufacture, import, sale, and use of the biosimilar, averting needless litigation. The parties negotiate over which listed patents to litigate immediately and which should be deferred to a second phase of litigation—for example, because the applicant may volunteer to wait for one or more patents to expire, the parties may agree to a patent license, or the applicant may avoid infringement by changing a

manufacturing parameter or seeking approval for only certain uses. The provision of a post-licensure marketing notice then creates a 180-day window for orderly proceedings on phase-two patents—those not singled out for immediate litigation, or those acquired after the sponsor initially identifies relevant patents—before the biosimilar enters the market. In the 180-day notice window, the sponsor can assess its phase-two patents with full information about the scope and terms of the biosimilar license, commence litigation, and (if appropriate) seek a preliminary injunction with adequate time for briefing, discovery, argument, and decision before the market is flooded with infringing biosimilars.

Sandoz's interpretation would replace that orderly process with chaos. Were Sandoz correct that an applicant can choose not to provide the initial disclosures or a marketing notice, a sponsor might not learn of the application for a potentially infringing biosimilar until the FDA licensed it. Even when the applicant chooses to notify the sponsor of the submission of its application, as Sandoz did, failure to disclose the application and manufacturing information will leave the sponsor without a clear understanding of which of its patents would be infringed. And if an applicant can provide a marketing notice at any time before licensure, as Sandoz argues, then the two phases of patent litigation could merge, become inverted, or splinter into a proliferation of patent suits.

In any of these scenarios, the applicant's concealment of information—both about the nature of its product and manufacturing processes, and about the anticipated timing of launch—would make it difficult for sponsors to seek injunctive relief and for courts to adjudicate such requests. The sponsor would thus be left sprinting to the courthouse with incomplete infor-

mation to seek an emergency injunction or temporary restraining order upon learning of an imminent or in-progress launch. Such emergency proceedings are burdensome for courts under any circumstances, and they are particularly burdensome and error-prone in complex patent cases. And even where sponsors manage to obtain emergency relief, it may come too late to protect them, since generic manufacturers often flood the market as soon as the FDA issues its approval. The resulting uncertainty would profoundly undermine the traditional incentives for innovation and investment that patents provide.

This Court often faces the unenviable task of choosing between a straightforward interpretation of a statute's text and structure and an alternative interpretation that better serves Congress's purpose. This case presents no such conundrum. Congress enacted a detailed framework for the orderly resolution of patent disputes involving biosimilars. The statute uses mandatory language, and Sandoz suggests no reason why compliance with the mandates is impossible or unworkable. Yet, rather than simply following the steps Congress laid out, Sandoz asks the Court to deem them all optional, obliterating Congress's goals of order and efficiency. The Court should instead enforce the statute Congress wrote.

OPINIONS BELOW

The court of appeals' opinion (Pet. App. 1a-55a) is reported at 794 F.3d 1347. The court of appeals' order denying rehearing (Pet. App. 85a-86a) is unreported. The district court's opinion (Pet. App. 56a-84a) is unreported but is available at 2015 WL 1264756.

JURISDICTION

The court of appeals entered judgment on July 21, 2015, and denied timely petitions for rehearing on October 16, 2015. In No. 15-1039, the Chief Justice extended the time to file a petition for certiorari to and including February 16, 2016, and Sandoz filed its petition on that date. Amgen timely filed its conditional cross-petition, No. 15-1195, on March 21, 2016. The Court granted both petitions on January 13, 2017. The Court's jurisdiction rests on 28 U.S.C. §1254(1).

The injunction that Sandoz challenges expired on September 2, 2015. Sandoz contends (at 26 n.5) that "the dispute between the parties remains live because it is capable of repetition yet evading review." Amgen is not privy to Sandoz's business plans or whether it intends to provide notice or disclosures to Amgen with respect to any future biosimilar applications.[1] Accordingly, Amgen cannot advise whether Sandoz's statement is properly understood as a representation that there is "a reasonable expectation or a demonstrated probability that the same controversy will recur involving the same complaining party." *FEC* v. *Wisconsin Right to Life, Inc.*, 551 U.S. 449, 463 (2007) (internal quotation marks omitted).

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[1] Amgen and Sandoz are currently litigating two other patent-infringement cases arising from biosimilar applications. In one—*Immunex Corp.* v. *Sandoz Inc.*, No. 16-cv-1118 (D.N.J.)—the FDA approved Sandoz's application in 2016 but Sandoz stipulated to a preliminary injunction against launch. In the other—*Amgen Inc.* v. *Sandoz Inc.*, No. 16-cv-2581 (N.D. Cal.)—the FDA responded without approving Sandoz's application in 2016; Amgen does not know the current status of that application.

STATUTORY PROVISIONS INVOLVED

Pertinent provisions of 21 U.S.C. §355, 28 U.S.C. §2201, 35 U.S.C. §271, and 42 U.S.C. §262 are reprinted in the appendix.

STATEMENT

A. The Biologics Industry

Biologics are groundbreaking medicines used to treat a range of complex and debilitating illnesses. Unlike traditional "small-molecule" drugs that are chemically synthesized, biologics are manufactured using living organisms. Congressional Research Service, *P.L. 111-148: Intellectual Property Provisions for Follow-On Biologics* (2010 CRS Report) 1 (2010). The resulting molecules are typically complex, and "'small differences between manufacturing processes can cause significant differences in the[ir] clinical properties.'" Congressional Research Service, *Follow-On Biologics: The Law and Intellectual Property Issues* 15 (2014).

Until 2010, a company seeking to market a therapeutic biologic could obtain FDA approval only by submitting a biologics license application under 42 U.S.C. §262(a). Under §262(a), the applicant must demonstrate that its biologic is "safe, pure, and potent." *Id.* §262(a)(2)(C)(i). This requires extensive laboratory data on the biologic's composition and properties, and information about its manufacturing processes and process parameters, as well as the results of typically three phases of human clinical trials. CAJA56; *see* 21 C.F.R. pt. 601. Developing a biologic and obtaining §262(a) approval requires an enormous investment. The process is highly risky, takes 10-15 years, CAJA57, and costs on average $1.2 billion, Pet. App. 41a n.1. As a result of the risk, costs, and sophisticated manufac-

turing techniques, biologics are generally more expensive than traditional drugs. 2010 CRS Report 1.

B. Statutory History

Seeking to "balanc[e] innovation and consumer interests," Congress enacted the BPCIA in 2010. Pub. L. No. 111-148, §7001(b), 124 Stat. 804, 804. Before the BPCIA, no streamlined approval pathway existed for "generic" biologics, as it did for generic small-molecule drugs under the Hatch-Waxman Act. The BPCIA created a streamlined pathway, drawing on certain features of the Hatch-Waxman Act but departing significantly with respect to others, due to the substantial differences between biologics and small-molecule drugs—including, most fundamentally, the inability to establish that one biologic is *identical* to another.

1. Enacted in 1984, the Hatch-Waxman Act created an expedited pathway allowing generic drugs to be approved on a showing that they are "bioequivalent" to an approved drug, without the need for clinical trials of safety or efficacy. 21 U.S.C. §355(j)(2)(A)(i), (iv).

The Act created several exclusivity periods during which the FDA cannot approve a generic version of the pioneer drug. A pioneer drug with a new active ingredient receives five years of exclusivity, 21 U.S.C. §355(j)(5)(F)(ii), and the pioneer can receive additional three-year exclusivity periods if it conducts clinical studies that support new conditions of approval or changes to the drug, *id.* §355(j)(5)(F)(iii)-(iv).

Separate from these periods of non-patent exclusivity, the Hatch-Waxman Act created procedures for the orderly resolution of patent disputes. The Act made the submission of an abbreviated new drug application an artificial act of infringement, and it created a mech-

anism for identifying relevant patents and resolving any claims before a generic's launch. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676-678 (1990).

Under the Hatch-Waxman Act's streamlined process, if an applicant disputes whether a patent is valid or infringed, the pioneering company has 45 days to file an infringement suit. If it does so, the statute automatically stays FDA approval of the generic drug for up to 30 months—thus imposing a mandatory waiting period that facilitates the resolution of patent disputes before the generic's launch. 21 U.S.C. §355(j)(5)(B)(iii).

2. By the early 2000s, the biologics industry had grown significantly.[2] Members of Congress became increasingly interested in adapting the Hatch-Waxman model to the biologics context, to promote competition while "preserving incentives for brand-name companies to develop new and innovative therapies." *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 110th Cong. 2 (2007) (statement of Rep. Pallone); *see Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary* (2009 Hearing), 111th Cong. 2 (2009) (explaining the need to "incentivize[] the extraordinary investment required to develop new biologics" while "not discourag[ing] biosimilar introduction" (statement of Rep. Johnson)).

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[2] 2010 CRS Report 1 (20% of available pharmaceuticals are biologics and some experts estimate nearly half of all newly approved pharmaceuticals will be biologics).

Congress recognized that biologics are significantly more complex than small-molecule drugs and are subject to the vagaries of manufacture in living organisms. Even a biologic that is *similar* to a pioneering product will necessarily be manufactured under different conditions, using different organisms and different manufacturing processes. As a result, a follow-on product cannot be shown to be *identical* to the pioneering product (as chemically synthesized generic drugs can). That difference has significant implications for patent disputes. For example, the patents a pioneering company can assert against one competing manufacturer may be quite different from the patents it can assert against another. And potentially applicable patents include not only composition and method-of-use patents, but also, importantly, process patents claiming techniques for producing, purifying, and testing the biologic. *See* 2009 Hearing 43, 97 (statement of Biotechnology Industry Organization (BIO)). These issues significantly influenced the framework Congress developed for identifying relevant patents and resolving disputes.

The House and Senate considered a range of alternative schemes that would provide notice of potentially applicable patents and a means for resolving disputes. Some bills proposed *optional* information-exchange and dispute-resolution procedures. *See* H.R. 1427, 111th Cong. §3(a)(2) (2009) (proposed §262(k)(18)(F)); S. 623, 110th Cong. §3(a)(2) (2007) (proposed §262(k)(17)(E)); H.R. 6257, 109th Cong. §3(a)(2) (2006) (proposed §262(k)(16)(E)). Under those proposals, a competing applicant could request information from the pioneering company about patents relevant to the original biologic. The applicant could then decide whether to provide a "notice" with a "detailed statement" explaining its position that particular patents were "invalid,

[were] unenforceable, or [would] not be infringed." H.R. 1427 §3(a)(2) (proposed §262(k)(18)(B)). The bills then envisioned two phases of litigation. The pioneering company could immediately sue the applicant on any patent for which the applicant had chosen to provide a notice. But it could not sue on any other patents until after the applicant had launched the product. *See, e.g., id.* (proposed §262(k)(18)(D)).

At the final congressional hearing on a streamlined biologics pathway, Congress heard testimony about the importance of a *mandatory* information-exchange procedure that would allow the pioneering manufacturer to "conduct [an] informed analysis" of whether any of its patents were implicated by an application for a similar product. 2009 Hearing 204 (statement of American Intellectual Property Law Association (AIPLA)). Witnesses also testified about the importance of resolving patent disputes before commercial marketing of a newly approved product. They explained that permitting a company to launch a competing product in the face of pending patent litigation would lead to "a longer period of uncertainty." *Id.* at 77 (BIO); *see also id.* at 201 (AIPLA).

Congress ultimately rejected the optional procedures contemplated by the bills discussed above. In 2009, the House passed a competing bill, which stated that the applicant "shall provide" its application and certain other information to the pioneering company. H.R. 1548, 111th Cong. §101(a)(2) (2009) (proposed §262(*l*)(4)(A)(i)); *see* Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 778 (2010). The Senate passed an amendment that likewise stated the applicant "shall provide" the required information to the pioneering company, and set forth a com-

prehensive two-stage framework for resolving patent disputes. *See* Carver 777. That amendment was modeled on S. 1695, 110th Cong. (2007), a compromise bill negotiated by the Senate Health, Education, Labor and Pensions Committee in 2007. Carver 776-777. As enacted, the BPCIA "largely tracks" the provisions of S. 1695. *Id.* at 746; *see also id.* at 806.

C. The Biologics Price Competition And Innovation Act

Congress enacted the BPCIA as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). The BPCIA establishes a streamlined approval pathway for biologics shown to be highly similar to approved products, 42 U.S.C. §262(k), accompanied by a series of steps to ensure the orderly resolution of patent disputes and the sponsor's opportunity to seek a preliminary injunction before launch of a follow-on product, *id.* §262(*l*).

Under the BPCIA's streamlined pathway, an applicant can submit an abbreviated biologics license application that "reference[s]" another company's previously approved biologic (the reference product). 42 U.S.C. §262(i)(4). If it does so, the applicant need not conduct a full complement of clinical trials, nor does the FDA require it to test the biosimilar for each of the reference product's licensed medical conditions. Instead, the FDA evaluates the application against the reference product and approves it if the applicant's product is "biosimilar to [the] reference product," meaning that it is "highly similar to the reference product" and there are "no clinically meaningful differences" between the two products with respect to "safety, purity, and potency." *Id.* §262(i)(2)(A), (B), (k)(2)(A)(i)(I). Biologics

for which streamlined approval is sought are known as biosimilars. 2009 Hearing 1.

The FDA may further designate a biosimilar as "interchangeable" with the reference product if the applicant meets additional safety criteria. An interchangeable biosimilar "may be substituted for the reference product without the intervention of the health care provider." 42 U.S.C. §262(i)(3). The first interchangeable product is guaranteed an exclusivity period during which the FDA cannot approve another biosimilar as interchangeable for the same reference product.

By design, the streamlined pathway means that companies can launch competing biologics without undertaking the same investment as pioneering companies. To help ensure that pioneering companies will continue investing in the development and approval of new biologics, the BPCIA carved out a period of time for each product during which applicants cannot take advantage of the streamlined pathway. Applicants cannot file biosimilar applications until four years after the FDA first licenses the reference product. 42 U.S.C. §262(k)(7)(B). And the FDA cannot make approval of a biosimilar effective until 12 years after first licensure of the reference product. *Id.* §262(k)(7)(A).

In effect, whereas a sponsor had previously enjoyed unlimited control over whether another company could rely on its product and clinical data to gain approval for a competing drug, the BPCIA limited that right to a 12-year data exclusivity period. As before, moreover, the sponsor is not guaranteed freedom from competition during the 12-year period: Other manufacturers are free to seek approval for competing products under §262(a)'s traditional pathway. One company, in

fact, obtained §262(a) approval for a filgrastim product—the same biologic at issue in this case.

Congress also protected the well-recognized incentives for invention by providing an orderly process for resolution of patent disputes between the applicant and the sponsor. Following the Hatch-Waxman model, the BPCIA created limits on declaratory-judgment actions concerning drug patents, 42 U.S.C. §262(*l*)(9), and amended the Patent Act to create an artificial act of infringement so as to facilitate adjudication of certain patent disputes during the streamlined approval process, 35 U.S.C. §271(e)(2)(C). The BPCIA then set forth an intricate series of steps—starting shortly after the FDA begins review of the biosimilar application—for parties to identify which patents are infringed and resolve disputes over the validity, enforceability, and infringement of those patents.

Unlike some earlier biosimilars bills, the BPCIA specified those steps in mandatory rather than discretionary terms. The process begins when the applicant chooses to submit an application under the streamlined pathway. The applicant "*shall* provide" the sponsor's counsel with "confidential access to the information *required* to be produced pursuant to paragraph (2)." 42 U.S.C. §262(*l*)(1)(B)(i) (emphases added). Within 20 days after the FDA accepts the application for review, the applicant "*shall* provide to the reference product sponsor a copy of [its] application ... and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." *Id.* §262(*l*)(2)(A) (emphasis added). It "*may* provide" additional information upon request. *Id.* §262(*l*)(2)(B) (emphasis added). The sponsor uses that information to determine which, if any, of

its patents might be infringed by the manufacture, use, import, or sale of the biosimilar. *Id.* §262(*l*)(1)(D).

The parties then conduct a series of exchanges about the relevant patents with the goal of narrowing and resolving potential disputes—whether through a license, an agreement to defer commercial marketing until a patent expires, or (if necessary) an infringement suit. Within 60 days after receiving the application and manufacturing information under §262(*l*)(2)(A), the sponsor "shall provide" to the applicant a list of patents that it could reasonably assert, identifying any that it would be willing to license. 42 U.S.C. §262(*l*)(3)(A). Within 60 days after receiving that list, the applicant "may provide" a list of additional patents that the sponsor could reasonably assert and "shall provide" a response with respect to each patent on the sponsor's list. *Id.* §262(*l*)(3)(B)(i), (iii). That response can consist of either a statement that the patent is invalid, unenforceable, or will not be infringed, or a commitment not to begin commercial marketing until the patent expires. *Id.* §262(*l*)(3)(B)(ii). Within 60 days after receiving the applicant's response, the sponsor "shall provide" its own statement with respect to the validity, enforceability, and infringement of each patent. *Id.* §262(*l*)(3)(C).

The sponsor and the applicant then determine which, if any, patents on their lists are appropriate subjects of an immediate infringement action. The parties first attempt to agree on the patents to be immediately litigated. 42 U.S.C. §262(*l*)(4)(A). If they fail to agree within 15 days, the applicant "shall notify" the sponsor of the number of patents it will designate for immediate litigation. *Id.* §262(*l*)(4)(B), (*l*)(5)(A). That number limits the number of patents the sponsor can list, unless the applicant designates no patents, in which case the sponsor can designate one. *Id.* §262(*l*)(5)(B)(ii). The

applicant and the sponsor then "simultaneously exchange" the lists of patents that each believes should be the subject of immediate litigation. *Id.* §262(*l*)(5)(B)(i). The sponsor "shall bring an action for patent infringement" of each patent identified on the parties' lists—the so-called phase-one patents—within 30 days after either the parties' agreement or the exchange of their separate lists. *Id.* §262(*l*)(6)(A)-(B).

Consistent with Congress's intent to facilitate efficient resolution of patent disputes, these provisions require the parties to identify patent claims that can meaningfully be adjudicated or otherwise resolved before the FDA determines what, precisely, will be licensed—including what active ingredient, what formulation, what uses, what delivery system, and what manufacturing processes. The sponsor and applicant may, for example, agree to litigate an obviously relevant composition patent, while deferring litigation on method-of-use and process patents that are only potentially relevant—either because the original application may be amended or supplemented during review or because there may be uncertainty about the uses for which the FDA will approve the biosimilar and about whether it will require the applicant to alter its manufacturing process.

The statute provides for a second, deferred phase of litigation concerning two sets of potentially applicable patents: (1) those identified in the exchanges but not chosen for immediate litigation in phase one; and (2) those issued to or exclusively licensed by the sponsor after the sponsor provides its original list, 42 U.S.C. §262(*l*)(7). Section 262(*l*)(7)'s provision for newly obtained patents accounts for the fact that pioneering companies continue to innovate long after the initial invention of the biologic itself—including by developing

new cell lines, therapeutic uses, formulations, and manufacturing processes. Companies often prosecute those patents over several years.

The trigger for the second phase of litigation is a notice that the applicant must provide to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. §262(*l*)(8)(A). Two consequences follow from that notice. First, before the applicant begins commercial marketing of the biosimilar, the sponsor can seek a preliminary injunction against its manufacture or sale until a court resolves disputes over the validity, enforceability, and infringement of the relevant patents. *Id.* §262(*l*)(8)(B). If the sponsor seeks a preliminary injunction, the sponsor and applicant "shall reasonably cooperate to expedite [any] further discovery" needed to resolve the motion. *Id.* §262(*l*)(8)(C). Second, the applicant or sponsor may bring a declaratory-judgment action as to the phase-two patents. *Id.* §262(*l*)(9)(A).

The statute restricts the availability of declaratory-judgment actions *before* the marketing notice. 42 U.S.C. §262(*l*)(9)(A). If an applicant "fails to provide the application and information required under paragraph (2)(A)," the applicant may not bring a declaratory-judgment action. *Id.* §262(*l*)(9)(C). Similarly, the applicant may not bring a declaratory-judgment action if it complies with §262(*l*)(2)(A) but fails to comply with certain subsequent obligations under §262(*l*). *Id.* §262(*l*)(9)(B). In other words, the applicant can bring a declaratory-judgment action only if it fully complies with § 262(*l*) and provides the marketing notice. The sponsor, by contrast, is not barred from bringing a declaratory-judgment action *unless* the applicant fulfills all of the specified obligations, in which case the spon-

sor must wait until it receives the marketing notice to bring such an action on phase-two patents. *Id.* §262(*l*)(9)(A).

D. Facts Of This Case

Amgen created and developed filgrastim, a biopharmaceutical version of a human protein known as granulocyte colony stimulating factor. Filgrastim stimulates the production of neutrophils, a type of white blood cell that fights infection.

In 1991, the FDA approved Amgen's §262(a) application to market filgrastim under the brand name Neupogen. Pet. App. 62a. The FDA initially approved Neupogen for the treatment of neutropenia, a white blood cell deficiency, in cancer patients undergoing chemotherapy. Through continued research and development, Amgen has since obtained FDA approval for additional therapeutic uses, including the promotion of faster engraftment for bone marrow transplant patients. *Id.* 63a. Amgen's patent on filgrastim itself has expired, but as of 2014 Amgen held an unexpired patent on a therapeutic use for filgrastim and on production and purification processes that could apply to the manufacture of filgrastim. CAJA472-473.

In May 2014, Sandoz filed an application under §262(k) for a biosimilar version of Neupogen, to be marketed as Zarxio. Pet. App. 8a. The FDA accepted Sandoz's application for review on July 7, 2014, *id.* 63a, triggering Sandoz's obligation under §262(*l*)(2)(A) to provide a copy of its application and manufacturing information within 20 days. Sandoz notified Amgen the following day that it had filed an application referencing Neupogen, but it refused to provide the information

required by §262(*l*)(2)(A). *Id.* 8a.[3] Instead, it stated that Amgen could file a declaratory-judgment action as permitted by §262(*l*)(9)(C). CAJA1496. Sandoz also informed Amgen that it intended to launch Zarxio immediately upon receiving FDA approval. CAJA1472.

E. District Court Proceedings

In October 2014, Amgen sued Sandoz in the Northern District of California. First, Amgen alleged that Sandoz had violated California's Unfair Competition Law (UCL)—which prohibits any "unlawful, unfair or fraudulent business act or practice," Cal. Bus. & Prof. Code §17200—by failing to comply with its duties under §262(*l*)(2)(A) and §262(*l*)(8)(A). CAJA73-75. Second, Amgen alleged that Sandoz's actions had unlawfully converted Amgen's Neupogen license for Sandoz's benefit by making use of the license under §262(k) without complying with §262(*l*). CAJA76-79. Finally, Amgen asserted infringement of U.S. Patent No. 6,162,427, which claims a method for using filgrastim to promote stem cell mobilization in stem cell transplant patients. CAJA79-80.

Sandoz counterclaimed for a declaration that applicants may choose not to provide their applications and

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[3] Sandoz offered to provide confidential access to its application—but not its manufacturing information—if Amgen agreed to terms different from those in the BPCIA. Among other things, the terms would have allowed Sandoz to redact any information Sandoz deemed irrelevant and would have restricted outside counsel's access. CAJA1465-1466, 1474-1478, 1498-1502. Given the discrepancies between Sandoz's proposed terms and the BPCIA's provisions, the district court correctly noted "there is no dispute that Sandoz did not engage in 42 U.S.C. §262's disclosure and dispute resolution process." Pet. App. 58a.

manufacturing information under §262(*l*)(2)(A), subject only to the declaratory-judgment consequences set forth in §262(*l*)(9). CAJA282-285. Amgen eventually obtained a copy of Sandoz's application, through discovery, on February 9, 2015—seven months after the FDA accepted Sandoz's application for review and six months after §262(*l*)(2)(A) required Sandoz to produce it. Pet. App. 63a.

Amgen moved for a preliminary injunction preventing Sandoz from marketing Zarxio, relying on its likelihood of success on its state-law claims. Dist. Ct. Dkt. 56 at 12-15. Sandoz moved to dismiss Amgen's state-law claims and moved for judgment on the pleadings on its counterclaims.

On March 6, 2015, while the motions were pending, the FDA approved Sandoz's application for Zarxio. Pet. App. 8a-9a. The approval letter noted that Sandoz had submitted over two dozen amendments to its application over the course of the FDA's consideration, but it did not disclose the substance of those amendments. CAJA1775. The approval letter authorized the use of Zarxio for the same indications as Neupogen and authorized Sandoz to manufacture Zarxio at facilities in Austria and Germany. CAJA1775-1776. Upon receiving the letter, Sandoz provided Amgen with "further notice" of its intention to begin commercial marketing. CAJA1774.

On March 19, 2015, the district court denied a preliminary injunction, dismissed Amgen's state-law claims, and entered judgment for Sandoz on its counterclaims relating to the interpretation of the BPCIA. Pet. App. 56a-58a. The court first held that an applicant may refuse to provide its application and manufacturing information, notwithstanding the mandatory

language in §262(*l*)(2)(A). *Id.* 68a-73a & n.6. If the applicant fails to provide that information, the court held, the sponsor can seek a declaratory judgment on the merits of its patent claims under §262(*l*)(9)(C). *Id.* 69a-70a. The court further held that Sandoz's initial notice of commercial marketing—provided the day the FDA accepted Sandoz's application—was legally effective because an applicant can give notice under §262(*l*)(8)(A) before obtaining FDA approval. *Id.* 73a-76a. Based on its conclusion that "Sandoz's actions did not violate the BPCIA," the court dismissed Amgen's state-law claims. *Id.* 77a. On March 25, 2015, the district court entered final judgment on the adjudicated claims to allow Amgen to file an appeal. CAJA20-23.

Sandoz agreed not to launch Zarxio until the earlier of May 11, 2015, or the Federal Circuit's decision on any request by Amgen for an injunction pending appeal. CAJA1946. The parties stipulated that further proceedings in the district court would be stayed until the issuance of the Federal Circuit's mandate. *Id.* Amgen agreed not to enforce its patents against Sandoz, and Sandoz agreed not to challenge the validity of those patents, during the period of any stay. *Id.*

F. Court Of Appeals Proceedings

On May 5, 2015, the Federal Circuit granted Amgen's motion under Federal Rule of Appellate Procedure 8(a) for an injunction prohibiting Sandoz from marketing or selling Zarxio during the appeal. C.A. Dkt. 105. After expedited briefing and argument, a divided panel of the Federal Circuit affirmed the district court's judgment in part and vacated it in part.

1. The panel unanimously held that an applicant's notice of commercial marketing under §262(*l*)(8)(A) is

effective only if given after the FDA licenses its product. Pet. App. 20a. The court relied on the statute's reference to commercial marketing of the "licensed" product, as well as the notice provision's purpose—namely, allowing the sponsor to assess the scope of the final license and "effectively determine whether, and on which patents, to seek a preliminary injunction from the court." *Id.* 20a-22a. The court rejected Sandoz's argument that requiring post-approval notice would improperly extend the 12-year period of exclusivity against biosimilar applications relying on the sponsor's data. *Id.* 22a.

A majority of the panel (Judge Lourie, joined by Judge Newman) held that it was appropriate to enjoin Sandoz from marketing Zarxio for 180 days after its post-licensure notice—until September 2, 2015. Pet. App. 31a. Judge Chen dissented from that holding. In his view, once an applicant refuses to provide its §262(*l*)(2)(A) disclosures, the remaining provisions of §262(*l*)—including the marketing-notice requirement—"cease to matter." *Id.* 43a.

2. A different majority (Judge Lourie, joined by Judge Chen) affirmed the district court's ruling that an applicant does not violate the BPCIA by refusing to provide its application and manufacturing information under §262(*l*)(2)(A). The majority agreed that the statutory text supports a mandatory construction of that provision. Pet. App 14a-15a. But it concluded that "'shall' in paragraph (*l*)(2)(A) does not mean 'must,'" on the theory that other provisions of the BPCIA "contemplate[]" the applicant's non-compliance. *Id.* 14a-16a. The majority held that a sponsor's only recourse in the event of the applicant's breach of §262(*l*)(2)(A) is to file a declaratory-judgment action on the merits of its patent claims under §262(*l*)(9)(C), or an infringement ac-

tion under 35 U.S.C. §271(e)(2)(C)(ii), or both. *Id.* 16a-18a.

Judge Newman dissented from that holding. Both the statute's plain text and its purposes of "avert[ing] and ... expedit[ing] litigation," she urged, show that "shall" in §262(*l*)(2)(A) means "shall," not "may." Pet. App. 35a-40a.

3. The court of appeals affirmed the dismissal of Amgen's state-law claims. It reasoned that Amgen could not state a UCL claim based on §262(*l*)(2)(A) because Sandoz had not acted unlawfully by withholding the specified information, and that a claim based on Sandoz's failure to give effective notice of commercial marketing under §262(*l*)(8)(A) was moot in light of the extended injunction. Pet. App. 26a-28a.

4. Both parties sought rehearing en banc. Amgen moved for a temporary injunction against the launch of Zarxio until the rehearing petitions were resolved. C.A. Dkt. 124. The Federal Circuit denied that request, C.A. Dkt. 128, and Sandoz began marketing Zarxio on September 3, 2015.

The Federal Circuit then denied both rehearing petitions. After the mandate issued, the parties agreed to lift the stay on district court litigation of Amgen's patent claims and Sandoz's patent-related counterclaims. Amgen amended its complaint to include an additional claim of infringement—namely that Sandoz's manufacturing process for Zarxio infringes U.S. Patent No. 8,940,878, which covers a method of purifying proteins. That patent, which had been under consideration by the Patent Office for years, did not issue until January 27, 2015. Discovery is ongoing, with trial scheduled for December 2017.

5. Both parties petitioned for a writ of certiorari, and the Court sought the views of the United States. After receiving the views of the United States, the Court granted both petitions.

While the petitions were pending, a different panel of the Federal Circuit (Judge Taranto, joined by Judges Bryson and Wallach) held that an applicant must give post-licensure notice of commercial marketing regardless of whether it complies with §262(*l*)(2)(A). *Amgen Inc.* v. *Apotex Inc.*, 827 F.3d 1052, 1066 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 591 (2016). Relying on the BPCIA's text, structure, and purpose—as well as this Court's precedents confirming the presumptive availability of injunctive relief—the Federal Circuit reaffirmed that a court may issue an injunction to enforce the applicant's duty to give post-licensure notice. *Id.* at 1063-1066.

SUMMARY OF ARGUMENT

1. Section 262(*l*)(8)(A) requires applicants to notify sponsors at least 180 days before "the first commercial marketing of the biological product licensed under subsection (k)." The statute's reference to a "licensed" product indicates that the notice must come after FDA licensure rather than before. Indeed, the reference to a "product licensed under" the streamlined pathway is unique in §262(*l*). Elsewhere, Congress referred to the biosimilar as a "product that is the subject of the [§262(k)] application." None of the provisions cited by Sandoz or the government overcomes this inference.

The structure of the BPCIA further supports reading §262(*l*)(8)(A) to require post-licensure notice. Section 262(*l*) divides patent litigation into two distinct phases—an immediate infringement action on patents

the parties deem appropriate for early resolution, and a subsequent action involving other patents. Allowing notice before licensure enables the applicant to collapse or even invert the two phases. The notice also authorizes the sponsor to seek a preliminary injunction against the launch of an approved biosimilar, preventing a change in the status quo during the adjudication of any remaining patent disputes. Congress did not mean to authorize preliminary injunction proceedings well before the sponsor is subject, as a result of the biosimilar's licensure, to the sort of concrete risk of harm that can justify an injunction.

Requiring applicants to provide post-licensure notice promotes §262(*l*)'s purpose of facilitating the orderly, pre-launch resolution of patent disputes. The biosimilar license granted by the FDA can differ significantly from both the reference product license and the license initially sought by the applicant. Modifications throughout the review process can easily affect the need for injunctive relief. Here, for example, Sandoz's application was amended 30 times. Sponsors need a post-licensure window to assess their patent rights, and determine whether to seek a preliminary injunction, once the scope of the applicant's permitted conduct is clearly defined by the biosimilar license.

Sandoz's interpretation would allow the applicant to provide notice at the time of submitting its application, often years before approval. A notice given in such circumstances is a notice in name only. In practice, it tells the sponsor nothing about when the biosimilar will be approved or, indeed, whether it is likely to be approved at all. A sponsor cannot seek injunctive relief against such a hazy risk of the biosimilar's launch; instead, it will have to rush to the courthouse to seek

emergency injunctive relief after learning of the biosimilar's licensure.

Because Sandoz claimed the right to launch its product fewer than 180 days after post-licensure notice, Amgen appropriately sought an injunction against that unlawful conduct under California's Unfair Competition Law. The Court need not address whether *federal* law independently authorizes an injunction requiring compliance with §262(*l*)(8)(A), because Amgen did not seek such relief. If it reaches that question, however, the Court should answer it in the affirmative. The BPCIA expressly authorizes sponsors to sue in federal court, and it does not limit the courts' inherent power to grant equitable relief for statutory violations in a properly filed suit. Whether the BPCIA creates a "private right of action" is the wrong question to ask—particularly given that, unlike in those cases that do address the availability of implied rights of action, the government does not enforce §262(*l*).

2. Section 262(*l*)(2)(A) states that an applicant "shall provide" the sponsor with a copy of its application and manufacturing information shortly after the FDA accepts its application for review. As the government recognizes, that is a command, not a choice. Nothing in the statute justifies departing from the ordinary, mandatory construction of the word "shall." To the contrary, neighboring provisions reinforce that construction by referring to the "information required" under §262(*l*)(2)(A) and by distinguishing it from information that the applicant "may" provide.

The BPCIA's purpose confirms what its text makes plain. Section 262(*l*)(2)(A) is an initial step in an intricate process for identifying and resolving patent disputes. By mandating early disclosure of the application

and manufacturing information, Congress ensured that the sponsor would have access to the facts necessary to identify patents it could reasonably assert against the applicant. Whether the parties engage in licensing negotiations, patent litigation, or both, the §262(*l*)(2)(A) disclosures enable the sponsor to narrow the dispute to patents that may actually be relevant. Sandoz's and the government's interpretation, by contrast, would force sponsors to sue on every potentially applicable patent and attempt to obtain the mandated information in discovery, or to add patents as discovery progresses. Such needlessly broad or evolving disputes are the opposite of what Congress had in mind. Indeed, Congress considered and rejected proposals that would have allowed the applicant to decide whether or not to participate in the dispute-resolution process.

Amgen appropriately sought an injunction under California's UCL to compel Sandoz to comply with §262(*l*)(2)(A). As with the marketing-notice provision, therefore, the Court need not decide whether federal law independently authorizes such an injunction. But if it reaches that question, the Court should answer it in the affirmative. Sandoz and the government principally argue that injunctive relief is inappropriate because two provisions allow a sponsor to file a declaratory-judgment or patent-infringement action if the applicant fails to provide the §262(*l*)(2)(A) information. But neither of those provisions purports to remedy the applicant's violation of §262(*l*)(2)(A), and neither provides a basis for concluding that §262(*l*)(2)(A) is unenforceable.

3. The error of Sandoz's interpretation is particularly clear in light of the *combined* effect of its positions on §262(*l*)(2)(A) and §262(*l*)(8)(A). Were Sandoz correct, the resolution of patent disputes relating to bio-

similars would diverge sharply from the orderly process Congress meant to create.

Under Sandoz's approach, a sponsor could be left totally in the dark about the existence of a pending application until the applicant launched its competing product upon receiving FDA approval. The sponsor would then have to rush to court to seek emergency injunctive relief on every potentially relevant patent, without having time to analyze the nature of the biosimilar and the scope of the FDA's approval, and without knowledge of the manufacturing process. The resulting proceedings would burden the courts by forcing them to decide complex disputes almost instantaneously. As experience with the Hatch-Waxman Act demonstrates, such compressed proceedings are arduous for the judiciary and unnecessarily prone to error.

The chaos caused by Sandoz's and the government's interpretation is reason enough to reject it. Amgen's interpretation of the statutory scheme is not merely more consistent with the statutory text and structure. It is also the only one that serves Congress's goal of promoting the orderly and efficient resolution of patent disputes.

ARGUMENT

I. APPLICANTS MUST PROVIDE 180-DAY MARKETING NOTICE AFTER LICENSURE

The Federal Circuit correctly (1) held that §262(*l*)(8)(A) requires applicants to provide a post-licensure notice at least 180 days before marketing, and (2) ordered Sandoz to comply with that mandatory obligation.

A. The Statutory Text Establishes That Notice Cannot Be Effective Until A Product Has Been Licensed

Section 262(*l*)(8)(A) states that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k)." (Emphasis added.) As the Federal Circuit observed, this reference to "'the biological product licensed under subsection (k)'" is unique within §262(*l*). Pet. App. 20a. Other provisions refer to "the biological product that is *the subject of*" the application. 42 U.S.C. §262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B) (emphasis added). That is a strong textual indication that §262(*l*)(8)(A), unlike the other provisions, refers to a product that has already been "licensed" by the FDA.

That conclusion is reinforced by the statute's use of "biological product licensed" in other subsections to refer to approved products. Section 262(d)(1), for example, authorizes the recall of "a batch, lot, or other quantity of a product licensed under this section" if it "presents an imminent or substantial hazard to the public health." And §262(i)(4) defines "reference product" as "the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." Both references make sense only as applied to products that have received FDA approval.

Sandoz's textual counter-arguments are unpersuasive.

First, Sandoz argues (at 31-32) that, because notice is to be given by "[t]he subsection (k) applicant," Congress could not have meant for notice to be given exclu-

sively by the holder of an approved application. In the context of §262(*l*)(8)(A), however, "[t]he subsection (k) applicant" simply distinguishes the party that submitted the application from the reference product sponsor. The statute defines the phrase in that manner. It states that "a person that submits an application under subsection (k)," as distinct from "the sponsor of the application for the reference product," is "referred to in" §262(*l*) "as the 'subsection (k) applicant.'" 42 U.S.C. §262(*l*)(1)(A). An applicant remains the "person that submits an application under subsection (k)" even after the application is approved. And contrary to Sandoz's claim (at 32) that "Congress refers to parties with approved applications as 'holders'" elsewhere in the statute, §262 uses the term "holder" only in reference to "the holder of an approved application *under subsection (a)*"—*i.e.*, the traditional pathway. 42 U.S.C. §262(m)(3) (emphasis added). The term is never used to describe recipients of streamlined biosimilar approval.

Second, Sandoz argues (at 35) that §262(*l*)(8)(A) refers to the "product licensed under subsection (k)" only to distinguish it from products that employ the traditional pathway, §262(a). But the provision already refers to "[t]he subsection (k) applicant." No further clarification is necessary.

Third, Sandoz argues (at 33-34) that §262(*l*)(8)(A) refers to the "product licensed under subsection (k)" only because the product will necessarily be licensed at the time it is marketed (whether or not it is licensed when the marketing notice is given). But that argument cannot be squared with other provisions of §262(*l*) that refer to a product that will be licensed as the "subject of the application" under subsection (k), not the "product licensed under subsection (k)." One provision, for example, requires the applicant to explain its view

that the sponsor's patents are "invalid, unenforceable, or will not be infringed by the *commercial marketing* of the biological product that is the *subject of the subsection (k) application*." 42 U.S.C. §262(*l*)(3)(B)(ii)(I) (emphases added); *see also id.* §262(*l*)(3)(C) (similar, regarding the position of the reference product sponsor). Congress clearly expected the product described in the application to be licensed before it was "commercially market[ed]," as marketing without licensure would be illegal. Sandoz is therefore wrong to suggest that the "subject of the application" language is limited to contexts where Congress expected the product would not yet be licensed. Rather, what harmonizes the statute's varying usage of the two phrases is that Congress employed the "subject of the application" language where the *act required by the statute*—in §262(*l*)(3)(B)(ii)(I) and (*l*)(3)(C), for example, the explanations by the sponsor and applicant—must occur prior to approval. By contrast, Congress used the "product licensed" formulation where the required act must occur after approval. That is the case with the marketing notice required by §262(*l*)(8)(A).

Sandoz responds (at 34) by citing 42 U.S.C. §262(k)(5)(C), which states that the FDA's "authority ... with respect to risk evaluation and mitigation strategies ... shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a)." Sandoz points out that a separate provision, 21 U.S.C. §355-1(a)(1), allows the FDA to require drug applicants to submit "a proposed risk evaluation and mitigation strategy" as part of the application. But the existence of that separate provision explains why Congress could refer in §262(k)(5)(C) only to "products licensed under" the streamlined pathway, knowing that

§355-1(a)(1) would extend that authority (where relevant) to products awaiting approval. No parallel provision extends §262(*l*)(8)(A)'s reference to "licensed" products to include products awaiting approval.

B. The Statutory Structure Confirms That The Marketing Notice Must Follow Licensure

The structure of §262(*l*) confirms that the marketing notice required by §262(*l*)(8)(A) must be provided after licensure.

First, §262(*l*) creates two phases of patent litigation. *See supra* pp. 14-16. Phase one, an "[i]mmediate patent infringement action" brought under §262(*l*)(6), can include only a limited set of patents—those the parties agree are appropriate for early litigation, §262(*l*)(4), or those specified under §262(*l*)(5) when the parties cannot agree. Phase two covers all remaining patents on the parties' §262(*l*)(3) lists, as supplemented under §262(*l*)(7) with patents later acquired or licensed by the sponsor. The marketing notice triggers the start of the second phase by lifting the bar on declaratory-judgment actions brought by either party, 42 U.S.C. §262(*l*)(9)(A), and by authorizing the sponsor to seek a preliminary injunction, *id.* §262(*l*)(8)(B).

If Sandoz were correct that the marketing notice could be given at any time, the phase-two litigation could subsume the phase-one litigation or even begin before it. It makes no sense to suggest Congress went to the trouble of distinguishing two phases of litigation—labeling only the first an "[i]mmediate patent infringement action," 42 U.S.C. §262(*l*)(6)—if it meant to allow applicants to collapse or invert that distinction and thus render meaningless the statutory framework, *id.* §262(*l*)(3)-(5), that produces the distinction.

Second, Sandoz's interpretation would allow applicants to upend §262(*l*)'s detailed rules about which party can institute litigation and at what time. If both parties complete the steps required by §262(*l*), then neither party can bring a declaratory-judgment action on phase-two patents until the post-licensure marketing notice issues. If the applicant fails to comply with §262(*l*), then the sponsor—but not the applicant—may bring an early declaratory-judgment action. But Sandoz's interpretation would allow the applicant to (1) provide the §262(*l*)(2)(A) disclosures, (2) simultaneously give its marketing notice, and (3) immediately file a declaratory-judgment suit on *all* patents in the venue of its choice—all before it is clear whether the applicant will follow the subsequent steps of §262(*l*). The applicant could then prevent §262(*l*)(9)(B) from applying, and thus maintain its chosen venue, by going through the motions on the remainder of the information exchange. Alternatively, the applicant might argue that even if it later violates one or more of its §262(*l*) duties, §262(*l*)(9)(B) does not bar an action that has already been brought. Either way, allowing premature marketing notice could invert the intended order of proceedings.

Third, the marketing notice is not just the trigger for declaratory-judgment actions on phase-two patents. It also authorizes the sponsor to "seek a preliminary injunction prohibiting the ... applicant from" manufacturing, importing, or selling its biosimilar product "until the court decides the issue of patent validity, enforcement, and infringement with respect to any" phase-two patent. 42 U.S.C. §262(*l*)(8)(B). Preliminary injunction proceedings by definition occur in exigent circumstances; no court can grant a preliminary injunction unless (among other things) the movant "is likely to suffer ir-

reparable harm in the absence of preliminary relief." *Winter* v. *NRDC, Inc.*, 555 U.S. 7, 20 (2008); *see also, e.g.*, *O'Shea* v. *Littleton*, 414 U.S. 488, 502 (1974) (among the "basic requisites of the issuance of equitable relief" is "the likelihood of substantial and immediate irreparable injury"). The fact that Congress made the marketing notice a trigger for preliminary injunction proceedings indicates that the notice must come after licensure, when the need for such relief is presented.

Fourth, because the marketing notice triggers the sponsor's right to seek an injunction, Congress must have expected that the notice would reflect the applicant's concrete expectation that marketing will occur. *See, e.g.*, *Winter*, 555 U.S. at 22 ("Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction."). Sandoz, by contrast, would allow an applicant to provide a "notice of commercial marketing" when it has nothing more than a *hope* that the FDA will approve its pending application. It is not clear how an applicant can provide "notice" of marketing when a condition precedent to marketing—namely, licensure—is wholly dependent on FDA action. And it is hard to imagine that Congress intended such a speculative "notice" to trigger injunction proceedings.

Fifth, the government posits (at 25) that "[a]n artificial-infringement claim cannot rest on a manufacturing-process patent alone." If that is correct, it is all the more critical that notice be provided after licensure, because the sponsor may be forced to bring any prelaunch claim for infringement of a process patent under the Declaratory Judgment Act, 28 U.S.C. §2201, seeking adjudication of a legal right based on 35 U.S.C. §271(a) or (g). In such circumstances, the sponsor will need to have notice at a time when it clearly signals

that a dispute is "'of sufficient immediacy and reality to warrant the issuance of a declaratory judgment,'" *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 127 (2007). Otherwise, sponsors seeking to prevent actual infringement of manufacturing patents under 35 U.S.C. §271(a) might have no way of knowing when they could assert such claims before launch.

Sixth, Sandoz's argument is difficult to square with §262(*l*)(7). That provision states that when an applicable patent "is issued to, or exclusively licensed by, the reference product sponsor" after the initial exchange of lists, "such patent shall be subject to paragraph (8)"—*i.e.*, treated as a phase-two patent. *See, e.g.*, *Apotex*, 827 F.3d at 1057. So long as the phase-two litigation is deferred until the applicant provides a post-licensure marketing notice, that litigation can include all patents the sponsor may acquire between the initial exchange of lists and the date of notice. But if the applicant could provide an early marketing notice, triggering phase-two declaratory-judgment actions before licensure, the litigation of later-acquired patents could be completely disordered. There could, for example, be a proliferation of patent suits filed as new patents issue or are licensed by the sponsor. Congress presumably did not mean to leave such a gaping hole in §262(*l*)'s otherwise comprehensive framework.

Finally, Congress expected a gap of roughly 180 days between licensure and marketing of a biosimilar product. Section 262(k)(6) provides an exclusivity period for the first biosimilar to demonstrate "interchangeability" with the reference product. That period ends with the first of five events, one of which is "1 year after the first commercial marketing of the first interchangeable" product, and another of which is "18 months after approval of" that product. 42 U.S.C.

§262(k)(6)(A), (C)(ii). The juxtaposition of those timeframes implies Congress expected a gap of roughly six months between approval and marketing.

Sandoz notes (at 37) that 180 days is slightly shorter than six months. But to the extent that difference is meaningful, it simply shows Congress gave the applicant a few days' grace period before terminating the incentive for achieving the first interchangeable product, in case the applicant cannot give notice the day it receives approval or launch exactly 180 days after notice. Sandoz also argues (at 37-38) that the interchangeability provisions "have nothing to do with the notice of commercial marketing," or with "commercial marketing of a biosimilar as a *biosimilar*," because they apply only when more demanding interchangeability requirements are satisfied. But interchangeable products are a subset of biosimilars, and Sandoz does not (and could not) suggest that §262(*l*)(8)(A) applies differently to interchangeable biosimilars than to biosimilars in general. Although Congress did not want all biosimilars to enjoy the exclusivity afforded to the first interchangeable product, §262(k)(6)'s timing provisions shed light on the anticipated gap between approval and commercial marketing for all biosimilars.

C. A 180-Day Notice Period Serves Congress's Purpose Of Ensuring Orderly Proceedings

Amgen's construction of §262(*l*)(8)(A) also advances Congress's purpose of providing an orderly process for the resolution of patent disputes.

1. Sandoz claims (at 39) that the purpose of the §262(*l*)(8)(A) marketing notice is to inform the sponsor "that commercial marketing will commence in *at least* 180 days." (Emphasis added.) By that account, the no-

tice serves no purpose at all. An applicant could give the notice at the time of filing its application, and all the notice would convey is that the biosimilar might be marketed in six months, or perhaps eight years, or perhaps never.

The actual purpose of the notice is to create a 180-day, pre-launch window for the two types of proceedings triggered by the notice—a declaratory-judgment action with respect to the phase-two patents, 42 U.S.C. §262(*l*)(9)(A), and preliminary injunction proceedings to delay the biosimilar's launch until patent litigation has been resolved, *id.* §262(*l*)(8)(B). This period is not, as Sandoz suggests (at 30), "delay for delay's sake." Rather, as the Federal Circuit observed, "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief," and "provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product." Pet. App. 21a. The 180-day window is critical to both litigants and courts.

The window is critical for litigants because, before licensure, the sponsor may not know whether the manufacture and sale of the approved biosimilar would infringe its patents. Even if an applicant (unlike Sandoz) discloses its application and manufacturing information as required by §262(*l*)(2)(A), the applicant may amend its application during the review process (as Sandoz did 30 times, CAJA1775), and the FDA may license fewer than all of the products included in a single application,

21 C.F.R. §601.9(c).[4] And where (as here) the applicant has *not* provided the §262(*l*)(2)(A) disclosures, the sponsor will have even less basis to know whether its patents are at risk. For example, a biosimilar applicant may seek approval for a different formulation than the reference product, a different delivery device, a subset of the reference product's routes of administration and conditions of use, or different manufacturing techniques. FDA, *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*, at 6-8 (2015).[5] All of those details can affect the infringement analysis.

Sandoz downplays (at 41) the need for a "'fully crystallized controversy'" as a "policy-based rationale," urging that Congress disagreed with that policy by authorizing "patent litigation well before ... FDA approval." But that argument—like Sandoz's more general statement (at 40) that Congress intended "to facilitate early resolution of patent disputes"—ignores Congress's choice to create two phases of patent litigation over biosimilars, not just one. Congress recognized that some patents can and should be litigated or licensed early, and it provided a detailed procedure for the parties to identify, negotiate, and litigate those pa-

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[4] Coherus's amicus brief suggests (at 16-17) that "the reference sponsor can propound discovery requests" in phase-two litigation "to monitor amendments to the biosimilar application, and should such an amendment impact the infringement analysis, it can add or remove patents from the case as appropriate." It is difficult to imagine Congress intended this "shoot first, ask questions later" approach to be part of an orderly dispute-resolution process.

[5] *Available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf.

tents. 42 U.S.C. §262(*l*)(4)-(6). But the marketing notice triggers the second phase of litigation, regarding patents the parties did *not* think were appropriate for immediate litigation.

Sandoz's argument also ignores the key difference between the concreteness of the dispute required to support an artificial-infringement action and the concreteness of the dispute required to support a preliminary injunction. Under 35 U.S.C. §271(e)(2)(C), an artificial-infringement action rests on the submission of an application and tests whether infringement would occur if the applicant were to engage in the full scope of conduct for which it seeks licensure. *Cf. Sunovion Pharm., Inc.* v. *Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1278-1279 (Fed. Cir. 2013) (Hatch-Waxman infringement judged against full scope of approval sought). The parties can thus litigate a phase-one action regarding the full scope of the license sought in the application, before it is clear what the applicant will actually be permitted to do, so long as the applicant's "*purpose* ... is to obtain approval ... to" sell, manufacture, or use a drug "claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. §271(e)(2) (emphasis added). If the sponsor prevails "in a final court decision" in such an action before the reference product exclusivity period has expired, the court must enjoin "any infringement of the patent." *Id.* §271(e)(4)(D). But if the phase-one litigation has not yet concluded by the time the FDA makes its approval effective—which is entirely possible—the sponsor cannot obtain a preliminary injunction against the manufacture, import, or sale of the licensed biosimilar without showing that the product, process, or use, *as licensed*, is likely to infringe its patents. A post-licensure marketing notice thus allows orderly injunctive proceedings not just with respect to phase-two

patents but with respect to phase-one patents still being litigated.

Whereas Amgen's interpretation of §262(*l*) would produce the order and efficiency Congress intended, Sandoz's would produce chaos. According to Sandoz, an applicant could give its marketing notice long before its product would ever be licensed, potentially as soon as it filed its application. But giving such an ill-defined time horizon for launch would make it exceedingly difficult for a sponsor to determine whether or when to seek an injunction. The sponsor could have trouble articulating why it was "likely to suffer irreparable harm in the absence of preliminary relief," why it was "likely to succeed on the merits," or why an injunction was "in the public interest," *Winter*, 555 U.S. at 20, without knowing the launch date of the biosimilar or the scope of FDA approval. *See, e.g.*, *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 111 (1983) (injunctive relief requires "a 'likelihood of substantial and immediate irreparable injury'").

The government recognizes as much. It agrees that a sponsor cannot seek preliminary injunctive relief "any significant amount of time before a biosimilar's commercial marketing," because "traditional equitable relief" is available only for those harms that "are sufficiently real and imminent." U.S. Br. 23-24; *see id.* at 31. Thus, the government frames the purpose of the §262(*l*)(8)(A) notice as "allow[ing] the sponsor to litigate its artificial-infringement claims on Round 2 patents in an action for declaratory relief and to seek injunctive relief *at an appropriate time in that action.*" *Id.* at 31 (emphasis added). But the government fails to answer the key question: Without a post-licensure marketing notice, how will the sponsor know when is "an appropriate time" to seek a preliminary injunction?

Under Sandoz's view, sponsors may not know the biosimilar's launch is sufficiently imminent to seek injunctive relief until the launch has actually occurred. The sponsor *might* learn about the biosimilar's licensure through a public announcement. But under Sandoz's interpretation, nothing would prevent the applicant from launching its product immediately upon licensure, since the marketing notice could have been given more than 180 days earlier. Sponsors would therefore have to seek injunctive relief on an emergency basis.

Congress did not envision that result. Section 262(*l*)(8)(B) authorizes sponsors to "seek a preliminary injunction" against the "commercial manufacture or sale of" the approved biosimilar "[a]fter receiving the notice" of commercial marketing "and *before* ... the first commercial marketing of" the biosimilar. (Emphasis added.) Congress saw no need for *post*-launch preliminary injunction proceedings, and its reference to preliminary injunctions rather than temporary restraining orders indicates that it expected there would be time for adversarial rather than ex parte proceedings. Post-launch proceedings would also impose an unfair burden on sponsors, who would have to explain why a preliminary injunction removing a product already on the market would serve "the public interest," *Winter*, 555 U.S. at 20.

2. Sandoz's construction would impose extraordinary burdens on district courts. The emergency proceedings that would be necessary under Sandoz's view would afford courts little time to examine potentially voluminous factual records and complex questions of patent law. Patents relating to biosimilars are among the most technical that a generalist judge is ever likely to encounter. For example, in Amgen's litigation

against Hospira over a biosimilar version of the biologic Epogen, one of the patents at issue "is directed to erythropoietin isoforms and erythropoietin compositions having specific numbers of attached sialic acid moieties, and methods for preparing the same." Complaint ¶71, Dkt. 1, *Amgen Inc.* v. *Hospira Inc.*, No. 15-cv-839 (D. Del. Sept. 18, 2015). Another "is directed to vertebrate cells which are capable of producing recombinant human erythropoietin, and processes for producing recombinant erythropoietin using such cells." *Id.* ¶75. It is difficult to imagine how a court conducting emergency proceedings, with no more than a few days or perhaps hours to issue a ruling, could sufficiently master the relevant issues to adjudicate patents like these.

Even when courts manage the burdens of emergency litigation, Sandoz's approach would hamper the efficacy of their remedial powers. Although there is little experience so far with biosimilars, manufacturers of traditional generic drugs have long positioned themselves to saturate the market with large quantities of generic drugs at the first opportunity. As an employee of AstraZeneca recently explained, "generic manufacturers commonly place six months or more worth of product into the market within days or hours of final approval." Decl. of Rod Wooten ¶19, Dkt. 22-2, *AstraZeneca Pharm. LP* v. *Burwell*, No. 16-cv-1336 (D.D.C. June 30, 2016).

Even a speedily issued preliminary injunction or temporary restraining order may not be quick enough to prevent large-scale market incursion by an infringing product. In 2008, for example, Teva obtained FDA approval to market its generic version of Pulmicort and launched immediately upon approval. By the time AstraZeneca secured a temporary restraining order

that same evening, Teva had flooded the market with approximately six months' worth of product. *Id.*; *see also* Dkt. 486 at 4, *Sanofi-Synthelabo* v. *Apotex Inc.*, No. 02-cv-2255 (S.D.N.Y. Oct. 19, 2010) (noting that Apotex shipped $884 million worth of a generic drug during the three weeks between launch and the issuance of a preliminary injunction). As the Federal Circuit has explained, "the [BPCIA's] legislative history confirms the aim to avoid the uncertainties and deficiencies associated with a process in which requests for temporary restraining orders and preliminary injunctions are presented and adjudicated on short notice." *Apotex*, 827 F.3d at 1063 (collecting numerous sources).

The Court should reject Sandoz's view that applicants may freely ignore the BPCIA's detailed dispute-resolution framework and substitute in its place the chaos Congress sought to avoid.

D. Courts May Order Applicants To Comply With The Notice Requirement

Section 262(*l*)(8)(A) is legally enforceable. Sandoz's contrary view would permit applicants to defy the 180-day notice requirement with impunity.

1. Injunctive relief is available under state law

The Court need not decide whether federal law authorizes an injunction to enforce §262(*l*)(8)(A), because Amgen sought an injunction not under federal law but under California's Unfair Competition Law (UCL). Amgen Opp. 28-29. The UCL provides that "[a]ny person who engages, has engaged, or proposes to engage in unfair competition may be enjoined in any court of competent jurisdiction." Cal. Bus. & Prof. Code §17203. Rather than "enforc[ing] the law on which a claim of

unlawful business practice is based"—here, the BPCIA—the UCL effectively "borrows violations of other laws and treats them as unlawful practices that [it] makes *independently* actionable" as a matter of state law. *Rose* v. *Bank of Am., N.A.*, 304 P.3d 181, 185 (Cal. 2013) (internal quotation marks omitted). Amgen relied on the UCL in seeking injunctive relief from the district court. CAJA73-75 (complaint); Dist. Ct. Dkt. 56 at 12-14 (preliminary injunction motion); *see* U.S. Br. 10.

"[R]espect for the States as 'independent sovereigns in our federal system' leads [courts] to assume that 'Congress does not cavalierly pre-empt state-law causes of action.'" *Wyeth* v. *Levine*, 555 U.S. 555, 565 n.3 (2009). As the party seeking dismissal of the state-law claims, Sandoz bears the heavy burden of overcoming the presumption against preemption. It has not even attempted to carry that burden, having affirmatively disavowed any preemption argument before the district court. *E.g.*, CAJA1854 ("We have not argued preemption of the state law claims.").

2. Injunctive relief is available under federal law

To the extent the Court addresses whether federal law authorizes an injunction requiring compliance with §262(*l*)(8)(A), it should reject Sandoz's position. That position would strip courts of traditional remedial authority and permit applicants to provide *no* notice of commercial marketing, or to violate their notice by entering the market before the 180-day period has run.

1. Sandoz primarily argues (at 43-45) that an injunction requiring compliance with the 180-day waiting period is unlawful because it would create a "private

right of action." But no one disputes that private litigants (including sponsors) have a right to sue under the BPCIA. The only question is whether, in the context of properly filed suits, courts may enforce the procedural framework enacted by Congress rather than allowing applicants to ignore it entirely.

That question does not implicate this Court's cases on private rights of action. Those cases address when private litigants—as opposed to the government—may sue to enforce a statute or regulation that does not expressly afford them that right. In *Alexander* v. *Sandoval*, for example, the question was "whether private individuals may sue to enforce disparate-impact regulations promulgated under Title VI of the Civil Rights Act of 1964." 532 U.S. 275, 278 (2001). The Court answered that question in the negative, explaining that, while "private individuals may sue to enforce ... Title VI" itself, Congress intended that regulations promulgated "'to effectuate'" the statute would be enforceable by the government alone. *Id.* at 279, 288-291.

This case presents no similar issue. As Sandoz recognizes (at 55), the government plays no role in enforcing the BPCIA's patent-dispute framework.[6] And the

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[6] The FDA has stated that the patent-dispute provisions "do not involve FDA." Approval Pathway for Biosimilar and Interchangeable Biological Products, 75 Fed. Reg. 61,497, 61,498 (Oct. 5, 2010). The FDA also denied a citizen petition, filed by Amgen, asking the FDA to require that all §262(k) applicants certify that they have provided sponsors with the information required by §262(*l*)(2)(A). Letter from Janet Woodcock to Jeffrey Kushan 3-4 (Mar. 25, 2015), *available at* http://patentdocs.typepad.com/files/citizen_petition_denial_response.pdf.

The lack of governmental enforcement distinguishes the cases on which Mylan's amicus brief relies (at 13-14) for the proposition

BPCIA expressly contemplates suits brought by sponsors. It defines the submission of a §262(k) application as actionable infringement, 35 U.S.C. §271(e)(2)(C); directs the sponsor to file an infringement action on phase-one patents, 42 U.S.C. §262(*l*)(6); sets forth a framework for declaratory-judgment actions on phase-two patents, *id.* §262(*l*)(9); and provides for sponsors to seek preliminary injunctions against the launch of an approved biosimilar, *id.* §262(*l*)(8)(B).

2. The only question, then, is the scope of available relief: In a properly filed suit, may a federal court order the applicant to comply with §262(*l*)(8)(A) by not marketing its product earlier than 180 days after a post-licensure marketing notice? This Court "long ago ruled that the federal courts' 'equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command,' whether 'in so many words, or by a necessary and inescapable inference.'" *Apotex*, 827 F.3d at 1064 (quoting *Porter* v. *Warner Holding Co.*, 328 U.S. 395, 398 (1946)). There is no contrary command, either explicit or implicit, in this case. Earlier bills addressing biosimilars *would* have limited the courts' power to compel compliance with patent-dispute resolution procedures. *See* H.R. 1427 §3(a)(2) (proposed §262(k)(18)(F)) (providing that applicant "may not be compelled, by court order or otherwise, to initiate the procedures set forth" in the patent dispute-resolution provisions); S. 623 §3(a)(2) (proposed §262(k)(17)(E)); H.R. 6257 §3(a)(2) (proposed §262(k)(16)(E)). But the BPCIA as enacted contains no such language.

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that a private right of action is unavailable to enforce certain provisions of the Hatch-Waxman Act.

Sandoz argues (at 53) that *Apotex* is wrong to presume the power to grant equitable relief, on the theory that the correct presumption weighs *against* the recognition of a private right of action. But that again confuses the existence of a right of action with the existence of equitable power in a properly filed action. Because no one questions that sponsors may bring suit, only the latter question is relevant here.

Sandoz also takes issue (at 54-55) with the particular authorities *Apotex* relied on for the proposition that courts generally possess power to enjoin violations of the law. But authorities for that proposition are legion. *E.g.*, *Califano* v. *Yamasaki*, 442 U.S. 682, 705 (1979) ("Absent the clearest command to the contrary from Congress, federal courts retain their equitable power to issue injunctions in suits over which they have jurisdiction."); *United States* v. *Paradise*, 480 U.S. 149, 183-184 (1987) (plurality opinion) ("'Once a right and a violation have been shown, the scope of a district court's equitable powers to remedy past wrongs is broad, for breadth and flexibility are inherent in equitable remedies.'"). Sandoz cannot seriously contend that district courts presumptively *lack* the power to remedy violations of the law in cases properly before them.

3. The BPCIA does not preclude an injunction requiring notice

1. Sandoz argues (at 46-48) that the BPCIA precludes injunctions to enforce §262(*l*)(8)(A) by specifying a particular consequence for a breach of that provision—namely the opportunity for the sponsor to "bring an action ... for a declaration of infringement, validity, or enforceability of any patent included in the list described in [§262(*l*)](3)(A), including as provided under

[§262(*l*)](7)." 42 U.S.C. §262(*l*)(9)(B). That argument fails for several reasons.

First, §262(*l*)(9)(B) does not purport to *remedy* a marketing-notice violation. Rather, the purpose of §262(*l*)(9) as a whole, and §262(*l*)(9)(B) within it, is to ensure that applicants cannot short-circuit the dispute-resolution processes of §262(*l*) by seeking declaratory relief. Under §262(*l*)(9), the applicant may initiate a declaratory-judgment action on phase-two patents in only one circumstance—once it has fully complied with its obligations under §262(*l*) and given marketing notice. Because the sponsor has no obligation to file an infringement action on any remaining phase-two patents, allowing the applicant to file a declaratory-judgment action at that point ensures that the applicant can obtain patent certainty before launch.

Sections 262(*l*)(9)(B) and (C) serve the converse purpose of preserving the sponsor's background right to file a declaratory-judgment action in all circumstances except one—where the applicant is fully complying with its obligations under §262(*l*). If the applicant participates fully in the dispute-resolution process, then the sponsor (like the applicant) must await the marketing notice to seek declaratory relief on phase-two patents. But §262(*l*)(9)(B) ensures that the applicant cannot diminish the sponsor's rights simply by refusing to comply with the marketing-notice requirement and §262(*l*)'s other obligations. This preservation of existing rights does not provide a remedy for a marketing-notice violation—and certainly does not purport to provide an *exclusive* remedy.

Second, §262(*l*)(9)(B) would be a wholly ineffective remedy for a marketing-notice violation, further confirming that Congress did not intend it to serve that

purpose. As Judge Taranto explained in *Apotex*, "relegating a reference product sponsor to a patent-merits declaratory-judgment action would introduce the very problem of rushed decision-making as to the patent merits that it is [§262(*l*)](8)(A)'s purpose to avoid." 827 F.3d at 1065. If the applicant launches its product without having given any marketing notice or without having waited the requisite 180 days after licensure, the sponsor is unlikely to learn of a breach of the notice requirement until launch has occurred. And when the sponsor does learn of the breach, it "will have to race to court for immediate relief" on a patent-infringement claim, forcing "the parties and the court ... [to] engage in precisely the hurried motion practice that [§262(*l*)](8)(A) is designed to replace by ensuring a defined amount of time for pre-launch litigation." *Id.* Such a "'remedy' is so gross a mismatch for the [§262(*l*)](8)(A) right that it cannot fairly be treated, in the absence of any statutory language so stating, as ... exclusive" of an injunction mandating compliance with the notice requirement. *Id.*

The Court should not interpret the BPCIA as creating a Catch-22 in which the exclusive remedy for a failure to give notice could be rendered meaningless by the failure to give notice. Courts should retain the authority to issue prospective injunctions *preventing* a breach of §262(*l*)(8)(A).

Third, §262(*l*)(9)(B) does not even apply in this case, given Sandoz's failure to provide the application and manufacturing information required by §262(*l*)(2)(A). As the structure of §262(*l*)(9) makes clear—and as both Sandoz (at 46) and the government (at 34-35) concede—§262(*l*)(9)(B) applies only where the applicant *complies* with §262(*l*)(2)(A) but "[s]ubsequent[ly]" fails to fulfill one of the other speci-

fied duties of §262(*l*). By contrast, §262(*l*)(9)(C) applies where the applicant fails to comply with §262(*l*)(2)(A). In cases like this one that are governed by subsection (C), not subsection (B), the statute simply does not specify a consequence for a breach of §262(*l*)(8)(A).

The government argues (at 35) that "specifically identifying" a declaratory-judgment "consequence for failing to give Section 262(*l*)(8)(A) notice is entirely unnecessary if the applicant failed at the outset to furnish the Section 262(*l*)(2)(A) information." "In those circumstances," the government says, "the BPCIA *already* provides that the sponsor may bring suit on any relevant patent." *Id.* That argument misses the point, however. Both Sandoz and the government lean heavily on the premise that §262(*l*) specifies a particular consequence for a breach of §262(*l*)(8)(A). But that premise is not correct where the applicant also breaches §262(*l*)(2)(A). Moreover, the provisions addressing a breach of §262(*l*)(2)(A) do not address the additional harm that occurs when an applicant also breaches §262(*l*)(8)(A) by launching without the required notice. *See supra* pp. 47-48.

Finally, as noted above (at 32), Sandoz's argument, that a marketing notice may be given at any time, would allow the applicant to circumvent §262(*l*)(9)'s framework for declaratory-judgment actions. Sandoz can hardly point to the sponsor's ability to file a declaratory-judgment suit under §262(*l*)(9)(B) as the exclusive consequence for a premature launch, when its interpretation could render that consequence toothless.

2. Alternatively, even if Sandoz were correct that the relevant question is whether §262(*l*)(8)(A) creates a right independently enforceable by a private litigant, that question should be answered in the affirmative.

As the Court explained in *Touche Ross & Co.* v. *Redington*, the task of determining whether the injured party may sue consists of "determining whether Congress intended to create the private right of action." 442 U.S. 560, 568 (1979); *see also, e.g.*, *Sandoval*, 532 U.S. at 286 ("The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy.").

For the reasons discussed above, it should be straightforward to conclude that Congress intended §262(*l*)(8)(A) to be enforceable by private litigants. The provision plays an essential role in the procedural framework Congress enacted, and the government does not enforce it. Denying courts the ability to enforce it by injunction, at the behest of private litigants, would render it a nullity. That would contravene this Court's "duty to give effect, if possible, to every clause and word of a statute," *Duncan* v. *Walker*, 533 U.S. 167, 174 (2001) (internal quotation marks omitted).

3. Sandoz argues (at 51-52) that Congress "expressly provide[d] an injunctive remedy" for a breach of §262(*l*)(1)'s confidentiality provisions, and that the Court should therefore infer it did not mean to provide such a remedy for a breach of §262(*l*)'s other provisions. But §262(*l*)(1)(H), which Sandoz characterizes as "provid[ing] an injunctive remedy," does nothing of the sort. Rather, it tells courts how to *apply* the traditional factors for equitable relief, by specifying that "[t]he disclosure of any confidential information ... shall be deemed to cause the ... applicant to suffer irreparable harm for which there is no adequate legal remedy," and that the court therefore "shall consider immediate injunctive relief to be an appropriate and necessary remedy for" such unlawful disclosures.

Section 262(*l*)(1)(H) thus supports Amgen's position on the availability of injunctive relief, not Sandoz's. It would make no sense for Congress to tell courts how to exercise their equitable power if Congress did not think the courts possessed such power.

4. The Federal Circuit did not reject the application of equitable factors

Contrary to Sandoz's argument (at 52), the Federal Circuit did not reject the proposition that an injunction against breach of §262(*l*)(8)(A) must be justified under the traditional factors for equitable relief. Although the Federal Circuit did not recite its application of the factors, there is no reason to think the court did not consider them. *See, e.g.*, *Hartman* v. *Nicholson*, 483 F.3d 1311, 1315 (Fed. Cir. 2007) ("That the court did not specifically mention the argument in its opinion forms no basis for an assumption that it did not consider it[.]" (internal quotation marks and brackets omitted)). To the contrary, since the parties briefed the application of the factors, both in the merits briefing and when Amgen sought an injunction pending appeal, the court presumably considered them. *E.g.*, Amgen C.A. Br. 62-65; Sandoz C.A. Br. 60-63.

Even if the Federal Circuit's failure to discuss the factors would otherwise be a basis to remand, there is no warrant for such factbound review here. The propriety of injunctive relief in this case is now moot; the injunction has expired, and Sandoz nowhere suggests this putative error is likely to recur in a case between the parties.

5. Post-licensure notice does not improperly extend the 12-year period of non-patent exclusivity

Sandoz argues (at 56-60) that courts cannot enforce the 180-day notice provision because doing so would effectively extend a 12-year period of exclusivity for reference products. That argument is unpersuasive for many reasons. Indeed, Sandoz itself proposed the dual system it now asks the Court to reject.

First, there is no conflict between the 180-day notice period and the text of §262(k)(7)(A), which states that the FDA's approval of a biosimilar application "may not be made effective ... until the date that is 12 years after the date on which the reference product was first licensed." Contrary to Sandoz's argument (at 57), the enforcement of a 180-day notice period does not render the FDA's "'effective' approval *ineffective* for six months." The approval remains effective—but it is only a necessary condition, not a sufficient one, for the applicant to begin marketing its biosimilar. A 180-day post-licensure notice period is a distinct prerequisite.

Second, there is nothing unusual about delaying the market entry of a drug to facilitate orderly patent litigation. That is precisely the approach taken by the Hatch-Waxman Act, which provides a 30-month period for the resolution of patent disputes between pioneering and generic drug manufacturers. *See supra* p. 8. That period is achieved through an automatic stay of FDA approval and routinely delays market entry beyond the separate, non-patent exclusivity periods provided by the Act. Compared to the automatic 30-month stay, the BPCIA's 180-day window for allowing the sponsor to seek a preliminary injunction is quite modest.

Indeed, Sandoz and its corporate parent (Novartis) proposed precisely such a system during the legislative process. Specifically, they proposed having an exclusivity period of at least 12 years and a separate, post-licensure notice period during which market entry would be delayed to facilitate patent litigation. The proposal appeared in a submission to the House Energy and Commerce Committee on behalf of the Novartis group of companies, including its "Sandoz generics business." Letter from Paulo Costa, Novartis Corp., to Reps. Pallone & Deal (May 1, 2008). The submission noted that, "[g]iven the investments necessary in developing innovator biologics, a minimum of 12 years of exclusivity is essential and there may be sound arguments for more." *Id.* attachment 30. It further explained that, although the companies would prefer for the BPCIA not to include patent provisions, "[o]ne proposal that may be useful for all stakeholders as part of the new pathway is if, immediately *subsequent to the FDA issuing the license* for a follow-on biologic, the reference product holder is given notice of say 45 or 90 days in which to initiate suit if they believe they have patents infringed; *during this window, the follow-on sponsor will not launch their product.*" *Id.* at 27 (emphases added); *see also id.* at 29 ("The follow-on sponsor *would be precluded from launch* for a set period, 45 or 90 days has been suggested as appropriate, during which the reference product sponsor could choose to litigate." (emphasis added)).

A Sandoz employee made a similar point in testimony before the relevant Senate committee. The "process for follow-on biologics," he stated, "could include a 45-day notification of an issued approval, during which time the innovator would be alerted to an approval referencing its product, and the innovator could institute

litigation if it believed that its patent or other intellectual property rights have been violated." *Follow-On Biologics: Hearing Before the S. Comm. on Health, Labor, & Pensions*, 110th Cong. 36 (2007) (statement of Dr. Ajaz S. Hussain, Vice President and Global Head of Biopharmaceutical Development, Sandoz).

Although Sandoz's precise proposal was not accepted, these comments contradict Sandoz's current view that setting aside a post-approval period for orderly patent litigation is somehow inconsistent with the BPCIA's structure or would improperly extend the non-patent exclusivity period.

Third, it is incorrect to regard the 12-year period created by §262(k)(7)(A) as a period of *market* exclusivity—*i.e.*, monopoly rights. It is simply a period of *data* exclusivity, during which the sponsor's clinical and product data on file with the FDA are protected and cannot be a basis for licensure of a biosimilar under §262(k)'s streamlined process. During the data-exclusivity period, competing biologics may be approved through the conventional pathway, §262(a), which requires the applicant to generate its own safety and efficacy data rather than relying on the sponsor's. For example, Teva obtained conventional approval for a competing filgrastim product, known as Granix, in 2012. *See* FDA, *List of Licensed Biological Products* (Feb. 16, 2017).[7]

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[7] *Available at* https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM439049.pdf.

Fourth, Sandoz incorrectly suggests (at 10, 56) that the 12-year period was the sole fulcrum on which Congress balanced the interests of pioneering drug innovators and biosimilar applicants. Although the term of data exclusivity was a subject of considerable debate in Congress, so was the statute's dispute-resolution procedure. *See* Carver 721-723, 735-737, 745-746, 755-761, 771-773, 782-784, 798-802, 813-816. Sandoz is wrong to suggest that, because Congress limited sponsors' data-exclusivity period to 12 years, the BPCIA's dispute-resolution provisions should be given a one-sided interpretation. Before the BPCIA, an applicant could never use the sponsor's data without its permission.

More broadly, Sandoz is wrong to assume that the interests of reference product sponsors and biosimilar applicants are monolithically at odds. Amgen, for instance, manufactures both reference products and biosimilars. *See, e.g.*, FDA, *FDA Approves Amjevita, A Biosimilar to Humira* (Sept. 23, 2016).[8] Amgen's interest is in enforcing the orderly framework that Congress enacted to benefit applicants and sponsors alike—not in procuring what Sandoz calls "delay for delay's sake" (Br. 30), which would harm Amgen's own biosimilars business.

Fifth, because Amgen's reference product was first approved more than 12 years before Sandoz filed its application, this case does not present the question of how the FDA might handle a situation in which the biosimilar applicant sought approval well before the expiration of the 12-year period. In *Apotex*, the Federal

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[8] *Available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm522243.htm.

Circuit speculated that the FDA might be able to "issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date," allowing the applicant to give its marketing notice 180 days before the end of the 12-year period. 827 F.3d at 1062. If the FDA possesses such authority and determines to exercise it—premises that will have to await clarification in a future case—that would negate Sandoz's concern about extending the 12-year period.

Sixth, Sandoz's argument that the 180-day notice period will give sponsors a windfall even if there are no patents to assert rests on an unproven assumption and misunderstands the provision's purpose. Unless a sponsor is no longer engaged in developing its reference product or improving its biologic manufacturing processes, it will be rare that a sponsor has no patents to assert. Innovation does not stop with the discovery of a new therapeutic molecule or a single method of manufacturing and using it. Sponsors commonly invent new methods of using a molecule to treat patients, new formulations, new methods of manufacturing and purification, and so on. And just as innovation does not happen overnight, neither does patent prosecution; once an application makes it through the Patent Office's massive backlog, the process of reviewing and refining claims can take years. Patents are an important foundation of pioneering companies' willingness to make the substantial and uncertain investments needed to invent new products, processes, and uses.

Because sponsors continue to innovate and because patent prosecution takes time, multiple patents have been asserted in each of the actions brought under the BPCIA so far. Here, for example, Amgen owned no unexpired patents for the filgrastim molecule itself when it sued Sandoz for infringement in 2014, but it

still held an unexpired patent claiming a method of using filgrastim to treat patients.

Sandoz also ignores the possibility that a sponsor that does not initially have a patent to assert may obtain one. Section 262(*l*)(7)(A) provides that, when a new patent "is issued to, or exclusively licensed by, the reference product sponsor," after the sponsor's initial patent list under §262(*l*)(3)(A), the sponsor may add that patent to the list of those potentially infringed by the biosimilar. When that happens, "such patent shall be subject to paragraph (8)." 42 U.S.C. §262(*l*)(7). That means it is treated as a phase-two patent, which cannot be the basis of a declaratory-judgment action until the marketing notice. Here, for example, Amgen obtained a process patent on January 27, 2015, and later amended its complaint to allege infringement of that patent. Because the patent issued more than three months after Amgen's §262(*l*)(3)(A) initial patent list would have been due had Sandoz complied with §262(*l*), that patent would have come under §262(*l*)(7).

Sandoz also ignores the fact that, even if the sponsor ultimately determines that none of its patents would be infringed, it may need time to make that determination given the complexity of the issues. The potential for a sponsor to decide not to assert any patents during the 180-day notice period does not negate the need for the period, so that the sponsor can make a considered and informed decision.

In any event, the possibility of a case in which the sponsor owns no applicable patents is not a reason to construe §262(*l*)(8)(A) in a manner that would undermine its functionality in the vast majority of cases. Congress often adopts bright-line rules without vary-

ing them for improbable events like the one Sandoz posits.

II. Applicants Must Provide Sponsors With Their Applications And Manufacturing Information

The Federal Circuit erred in holding that applicants may refuse to comply with §262(*l*)(2)(A)'s requirement to disclose their applications and manufacturing information. In reaching that conclusion, the court unjustifiably read the phrase "shall provide" in §262(*l*)(2)(A) as discretionary rather than mandatory—a construction that conflicts not only with the court's interpretation of the same phrase in §262(*l*)(8)(A), but also with the statutory text and purpose.

A. The Statutory Text Establishes That Disclosure Is Mandatory

Section 262(*l*)(2)(A) provides that, no later than 20 days after the FDA notifies the applicant that its application has been accepted for review, the applicant "*shall* provide to the reference product sponsor a copy of [its] application" and "other information that describes the process or processes used to manufacture the biological product." (Emphasis added.) As this Court has repeatedly held, "'shall' is ordinarily 'the language of command.'" *Alabama* v. *Bozeman*, 533 U.S. 146, 153 (2001); *see also, e.g.*, *State Farm Fire & Cas. Co.* v. *United States ex rel. Rigsby*, 137 S. Ct. 436, 442 (2016) ("'[S]hall' ... creates a mandatory rule the relator must follow.").

The text of §262(*l*)(2) provides no reason to deviate from the typical, mandatory meaning of the word "shall." To the contrary, the statute contrasts §262(*l*)(2)(A)'s directive that the applicant "*shall* provide" its application and manufacturing information

with §262(*l*)(2)(B)'s provision that the applicant "*may* provide ... additional information requested by or on behalf of the reference product sponsor." (Emphases added.) "[W]hen the same [statute] uses both 'may' and 'shall,' the normal inference is that each is used in its usual sense—the one act being permissive, the other mandatory." *Anderson* v. *Yungkau*, 329 U.S. 482, 485 (1947); *see also, e.g.*, *United States ex rel. Siegel* v. *Thoman*, 156 U.S. 353, 360 (1895) (the use of "shall" and "may" "indicat[es] command in the one and permission in the other").

The separate provision governing the confidentiality of the dispute-resolution process further underscores this contrast. It distinguishes between "the information *required* to be produced pursuant to paragraph (2)" and "any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate." 42 U.S.C. §262(*l*)(1)(B)(i) (emphasis added).

Other provisions likewise reinforce that Congress viewed §262(*l*)(2)(A) as a command. Section 262(*l*)(9) twice refers to "the application and information *required*" under §262(*l*)(2)(A). (Emphasis added.) So does 35 U.S.C. §271(e)(2)(C)(ii). Those provisions further refer to an applicant's "*fail[ure]*" to provide the "required" information. If Congress understood §262(*l*)(2)(A) as permissive, it would instead have used language reflecting as much, as it did in other provisions. *E.g.*, 42 U.S.C. §262(*l*)(1)(F) (noting that the sponsor can "opt[]" to destroy confidential information instead of returning it).

The Federal Circuit nonetheless held that "'shall' in paragraph (*l*)(2)(A) does not mean 'must.'" Pet. App. 15a. The government notably does not defend that

holding. U.S. Br. 16 (agreeing that Federal Circuit "misconceived the relevant inquiry"). The Federal Circuit appeared to reason that §262(*l*)(2)(A) cannot impose a mandatory obligation because two other provisions "explicitly contemplate[]" the applicant's noncompliance by allowing a sponsor to bring a declaratory-judgment or patent-infringement action if the applicant fails to provide the §262(*l*)(2)(A) information. Pet. App. 15a (citing 42 U.S.C. §262(*l*)(9)(C); 35 U.S.C. §271(e)(2)(C)(ii)).

But neither of those provisions supports the inference that §262(*l*)(2)(A) is optional. Rather, they simply ensure that the sponsor is not denied access to the courts by the provisions of the BPCIA in the event of an applicant's non-compliance. And the fact that a statute "contemplates" possible noncompliance does not render compliance optional. For example, Federal Rule of Civil Procedure 37(c)(1) provides for various consequences if a party "fails to provide information or identify a witness as required by Rule 26(a)." Yet no one would characterize Rule 26(a)'s disclosure obligation as anything but mandatory. *See* Fed. R. Civ. P. 26(a)(1)(A) (party generally "*must*, without awaiting a discovery request, provide" certain information (emphasis added)).

B. The Statutory Purpose And Legislative History Confirm That Disclosure Is Mandatory

Construing §262(*l*)(2)(A) as mandatory advances an important congressional purpose—promoting the orderly resolution of patent disputes—in several ways.

First, §262(*l*)(2)(A) enables the sponsor to identify and narrow the list of patents implicated by the application. As Congress recognized, process patents—

those covering methods of purification or production—are particularly important in the biologics context. *Supra* p. 9. Without access to the applicant's manufacturing information, the sponsor cannot know whether the applicant's manufacturing process will practice its process patents. Furthermore, a biosimilar is only *similar* to the reference product; it need not have the same structure or formulation. *Id.* Without access to the biosimilar application, the sponsor may not know whether the biosimilar incorporates all the patented features of the reference product. Nor will it know whether the application is seeking approval for all existing indications or routes of administration or only a subset. The §262(*l*)(2)(A) disclosures give the sponsor the information necessary to determine which patents could be infringed.

The Federal Circuit downplayed the significance of §262(*l*)(2)(A) by suggesting that a sponsor can "access the required information through discovery" after filing suit. Pet. App. 17a. But the statute *entitles* the sponsor to this information, without delay or the burden of discovery disputes. Moreover, recent experience shows that accessing the information in discovery is uncertain and not an adequate substitute for timely, mandatory disclosure. In *Amgen Inc.* v. *Hospira, Inc.*, the applicant provided its application to the sponsor but refused to provide other manufacturing information. Appellant's Br. 8-10, Dkt. 28, No. 2016-2179 (Fed. Cir. Sept. 12, 2016). Unable to determine whether its manufacturing patents could reasonably be asserted, the sponsor sued on certain other patents and sought manufacturing information in discovery. *Id.* But the district court refused to compel production, deeming the requests irrelevant to the patent claims in suit. *Id.* at 12-13. If that erroneous understanding prevails in oth-

er courts, the only way for a sponsor that does not receive the §262(*l*)(2)(A) disclosures to protect its patent rights would be to throw professional caution to the wind and sue on *every* conceivably relevant patent—something sponsors will be reluctant to do. *Cf.* 2009 Hearing 208 (AIPLA) (noting that, without mandatory information-exchange provisions, a sponsor might lack a good-faith basis to assert certain patents).

Second, Sandoz ignores the role §262(*l*)(2)(A) plays within §262(*l*)'s broader dispute-resolution process. As described above, requiring the applicant to disclose its application and manufacturing information at the outset allows the sponsor to narrow the list of patents that could potentially be infringed by the biosimilar. The §262(*l*)(2)(A) disclosures also facilitate the next several steps in the process, which require the parties to exchange their respective positions on the validity, enforceability, and infringement of the patents the sponsor identifies—further narrowing the scope of the dispute. 42 U.S.C. §262(*l*)(3). Indeed, the disclosures may enable the parties to avert litigation by resolving their dispute through other means. The parties must, for example, exchange positions on their willingness to license specific patents. *Id.* §262(*l*)(3)(A)(ii), (B)(iii). And an applicant must decide whether to dispute each patent or simply agree to delay commercial marketing until the patent expires. *Id.* §262(*l*)(3)(B)(ii). These provisions, which depend on the applicant's §262(*l*)(2)(A) disclosures, reduce litigation and streamline it where it occurs.

Third, allowing an applicant to opt out of the information-exchange process would not only undermine the goal of informed and efficient dispute resolution; it would also unfairly limit the sponsor's remedies on patent-infringement claims. Section 271(e)(4)(D) enables a

sponsor to obtain a mandatory permanent injunction against infringement if (1) the reference product remains within the 12-year exclusivity period and (2) a court has adjudicated the dispute "in an action for infringement of the patent *under* [*§262*](*l*)*(6)*." (Emphasis added.) An applicant that refuses to provide the information mandated by §262(*l*)(2)(A) can preclude the possibility of a §262(*l*)(6) action, unilaterally depriving the sponsor of the right to obtain a mandatory injunction.[9]

Finally, Congress considered and rejected a permissive rather than mandatory patent dispute-resolution scheme. An early proposal for a biosimilar pathway would have specified that "[t]he decision as to whether to invoke the [patent dispute-resolution] procedures ... is left entirely to the discretion of the applicant." H.R. 6257 §3(a)(2) (proposed §262(k)(16)(E)). Two of the BPCIA's other predecessor bills—including one that remained under debate at the final House committee hearing—expressly provided that "[n]othing" in the statute "require[d] an applicant ... to invoke" the patent dispute-resolution procedures. H.R. 1427 §3(a)(2) (proposed §262(k)(18)(F)); S. 623 §3(a)(2) (proposed §262(k)(17)(E)). Similarly, earlier discussion

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[9] The government argues (at 25-26) that the availability of a mandatory injunction "compensat[es]" the sponsor as a "counterbalance" for the applicant's control over the number of patents that can be litigated in a §262(*l*)(6) suit. But the government overstates the degree to which the applicant controls the scope of the phase-one litigation: The sponsor can always designate at least one patent for immediate litigation, and it can obtain a mandatory injunction if that patent is held infringed. Furthermore, a sponsor can also initiate litigation under §262(*l*)(6)—and thus obtain a mandatory injunction—if the parties *agree* on which patents to litigate. 42 U.S.C. §262(*l*)(4)(A), (*l*)(6)(A).

drafts of S. 1695—the bill on which the BPCIA was modeled, *see supra* p. 11—would have given the sponsor and the applicant "the option to notify each other regarding patents they deemed relevant." Carver 757.

In enacting the BPCIA, Congress abandoned such discretionary language and replaced it with a series of commands. This Court "ordinarily will not assume that Congress intended 'to enact statutory language that it has earlier discarded in favor of other language.'" *Chickasaw Nation* v. *United States*, 534 U.S. 84, 93 (2001). That would be the effect of adopting Sandoz's permissive construction of §262(*l*)(2)(A).

C. Courts May Order Applicants To Comply With The Disclosure Requirement

Sandoz and the government contend that, even if §262(*l*)(2)(A) mandates disclosure, a court may not order an applicant to comply.

As discussed above (at 42-43) in reference to §262(*l*)(8)(A), this Court need not decide whether federal law authorizes an injunction to enforce §262(*l*)(2)(A). Sandoz agrees that no party has sought such an injunction under the BPCIA. Sandoz Opp. 2. Amgen instead sought injunctive relief under California's UCL. And Sandoz has disavowed any claim that the UCL, or the scope of relief under it, are preempted. *Supra* p. 43.

In any event, federal law *does* authorize injunctions to enforce §262(*l*)(2)(A), for the same reasons it authorizes injunctions to enforce §262(*l*)(8)(A). *See supra* pp. 43-46. Whether or not the BPCIA confers a private right of action, it does not limit the courts' inherent power to grant equitable relief in a properly filed suit. *See supra* pp. 45-46. And even if the Court were to

reach the question whether the BPCIA confers a private right of action, it should have little difficulty concluding that Congress intended for the §262(*l*)(2)(A) duty to be enforceable, since the alternative would be to assume Congress enacted a functionally meaningless provision.

Sandoz and the government argue that Congress tied the courts' hands by specifying two consequences of a §262(*l*)(2)(A) violation, to the exclusion of others—namely, a declaratory-judgment action permitted by §262(*l*)(9)(C) and a patent-infringement suit under §271(e)(2)(C)(ii). Sandoz Opp. 26-27; U.S. Br. 17-19. Neither provision, however, purports to provide any remedy at all—let alone an exclusive remedy—for a §262(*l*)(2)(A) violation.

First, §262(*l*)(9)(C) simply allows the sponsor to go forward with a declaratory-judgment action (by lifting the bar imposed by §262(*l*)(9)(A)) if the applicant fails to make the disclosures required by §262(*l*)(2)(A). Ordinarily, §262(*l*)(9)(A) prevents both the sponsor and the applicant from seeking declaratory relief on phase-two patents before the applicant's provision of a marketing notice. But if the applicant refuses to initiate the information-exchange process that leads to a division among phase-one and phase-two patents, it makes no sense to force the sponsor to await the outcome of a process that cannot occur. The practical utility, if any, of the declaratory-judgment action depends on the sponsor's ability to identify an infringed patent without the required disclosures. But if the sponsor *can* identify certain patents as infringed, it should be able to bring an action with respect to those patents and seek an order compelling the applicant to comply with §262(*l*)(2)(A), so as not to delay the sponsor from litigating its patents prior to launch. Section 262(*l*)(9)(C)

thus accomplishes the limited and necessary purpose of eliminating a nonsensical obstacle to the sponsor's assertion of its patent rights. It does not purport to state the exclusive consequence of a §262(*l*)(2)(A) violation.

Second, the Federal Circuit relied on 35 U.S.C. §271(e)(4), which lists the "only remedies" a court may award for "*an act of infringement* described in" §271(e)(2). (Emphasis added.) Section 271(e)(2), in turn, makes it an "act of infringement to submit ... an application seeking approval of a biologic[] ... if the purpose of such submission is to obtain approval ... to engage in the commercial manufacture, use, or sale" of a biologic in a manner that would infringe a patent covering the biologic or a method of using it. 35 U.S.C. §271(e)(2)(C). In general, the patents infringed by the submission are those identified by the parties under §262(*l*)(3) and (*l*)(7). *Id.* §271(e)(2)(C)(i). But if the applicant fails to provide the disclosures required by §262(*l*)(2)(A)—and, consequently, there is no comprehensive list of patents generated by §262(*l*)(3)—the submission infringes any patents that *could have been identified* under §262(*l*)(3). *Id.* §271(e)(2)(C)(ii). The Federal Circuit reasoned that the relevant "act of infringement" under §271(e)(2)(C) must be the submission of an application "coupled" with the failure to provide the required disclosures—and therefore that §271(e)(4) specifies the exclusive remedies for a breach of §262(*l*)(2)(A). *Apotex*, 827 F.3d at 1061; *see also* Pet. App. 18a.

But that reading of the statute is incorrect. As in the Hatch-Waxman context, the artificial act of infringement created by §271(e)(2)(C) is the *submission of the application*. *Cf. Eli Lilly*, 496 U.S. at 678 (noting that the "act of infringement" under the Hatch-Waxman Act "consists of submitting an abbreviated

new drug application"). The applicant's violation of §262(*l*)(2)(A) is not an act of infringement; it informs how the *scope* of the infringement is to be determined—that is, which patents are implicated by the submission. If the parties have engaged in the §262(*l*) process, §271(e)(2)(C)(i) deems infringed any patents identified under §262(*l*)(3). But where the applicant prevented the parties from reaching that stage by failing to comply with §262(*l*)(2)(A), all patents that *could* have been identified are deemed infringed. Because a breach of §262(*l*)(2)(A) is not an act of infringement, §271(e)(4) does not specify the exclusive remedies for it.

III. The Combined Effect Of Sandoz's Positions Illustrates Why Those Positions Are Incorrect

Sandoz's interpretations of §262(*l*)(2)(A) and §262(*l*)(8)(A) are incorrect even when those provisions are considered separately, as explained above. But the implausibility of Sandoz's view becomes even clearer in light of the combined effect of its positions.

1. In the most extreme case, Sandoz's interpretation would leave a sponsor unaware of the application until the day the FDA announces its approval. In Sandoz's view, an applicant could choose not to provide the disclosures required by §262(*l*)(2)(A), *and* refuse to provide at least 180 days' notice of commercial marketing. Sandoz Br. 60-62; U.S. Br. 32-33. The sponsor's only option to enforce its patent rights in that scenario would be to seek emergency injunctive relief after licensure, while the applicant seeks to rush onto the market.

Even after FDA approval, however, a sponsor would still lack information about the applicant's manufacturing process and might lack other pertinent infor-

mation, including about the biologic's structure. *See, e.g.*, 21 C.F.R. §601.51(f) (biologic's manufacturing information is "not available for public disclosure" even after approval). As a result, the sponsor might be unable to narrow the list of potentially relevant patents, leading to needlessly complex disputes on an emergency timeline. The government, like the Federal Circuit, dismisses this problem (at 25) by suggesting the sponsor can sue on some patents and obtain the §262(*l*)(2)(A) information through discovery. But that process is neither simple, nor certain, nor speedy. *See supra* pp. 61-62.[10]

Even if the sponsor obtains the application and manufacturing information in discovery, that would leave it virtually no time to analyze the technical detail, assess its patents, decide which patents to assert, and seek a temporary restraining order and preliminary injunction. Only then could the parties begin to litigate the claim construction, validity, enforceability, and infringement issues necessary to assess the sponsor's likelihood of success on the merits.

Such proceedings would impose crushing burdens on already busy courts and lead to rushed decisions on exceedingly complex disputes—exactly the opposite of the orderly process Congress intended. The Hatch-Waxman experience is again instructive. District courts forced to decide whether to grant emergency relief on compressed timetables have denied prelimi-

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[10] The sponsor's inability to identify manufacturing-process patents that might be infringed would be exacerbated if, as the government contends (at 25), a sponsor can sue for artificial infringement only on patent claims covering compositions and uses of biosimilars.

nary injunctions and allowed generics to launch, only to have the patents subsequently be found valid and infringed.[11] The risk of similar errors is exacerbated if the sponsor must seek emergency relief on the day of launch without even knowing the relevant patents.

2. Sandoz contends (at 48-51) that sponsors will not be left in the dark. It points to a handful of ways a sponsor *might* learn about pending applications, including securities filings, an FDA clinical trial database, FDA advisory committee meetings, and voluntarily issued press releases. There is, of course, no indication that Congress intended for sponsors to have to scour these sources for information. On the contrary, Congress provided a simple way for sponsors to be notified about a pending application: It stated that applicants "shall provide" their applications to sponsors under §262(*l*)(2)(A).

Even if the statute placed the burden on sponsors to monitor available sources of public information, none of those sources would necessarily provide the sponsor with effective notice. An applicant might be a privately held company with few, if any, securities disclosure obligations, and even a publicly traded applicant might determine that filing the application is not sufficiently material to warrant disclosure. The clinical trial database will yield no information where, for example, the FDA exercises its discretion to deem a clinical trial unnecessary for a particular application,

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[11] Dkts. 151, 319, *Sanofi-Aventis Deutschland GmbH* v. *Glenmark Pharm. Inc., USA*, No. 07-cv-5855 (D.N.J. Jan. 14, 2011); Dkts. 249, 821, 1384, *Altana Pharma AG* v. *Teva Pharm. USA, Inc.*, No. 04-cv-2355 (D.N.J. Apr. 23, 2010); *see also* O'Malley et al., *Failure to Launch*, Intell. Prop. Mag. 30-32 (Apr. 2011).

42 U.S.C. §262(k)(2)(A)(ii), or where clinical trials were conducted abroad and therefore not included in the database. Nothing in §262(k) requires the FDA to hold an advisory committee meeting before approving every biologic. *Cf.* 21 U.S.C. §355(s)(2) (FDA need "not refer the drug to advisory committee prior to approval" if it provides "a summary of the reasons ... in the action letter on the application"). And an applicant can always decide not to issue a press release.

Moreover, even if sponsors might learn about the *existence* of an application through other channels, that is not enough. A sponsor will not know the application's particulars or the relevant manufacturing information, without which the sponsor may have difficulty determining which patents are potentially infringed. *See supra* pp. 60-61. And without the §262(*l*)(8)(A) notice, the sponsor will not know when commercial marketing will begin—and thus when to seek a preliminary injunction against the biosimilar's launch.

Sandoz and the government suggest that upon learning of the existence of an application—which could be years before the commercial marketing of a biosimilar—the sponsor should seek declaratory relief on any patent *potentially* infringed by the manufacture, sale, import, or use of the biologic. Without the disclosure mandated by §262(*l*)(2)(A), the result could be a needlessly broad action asserting dozens or hundreds of patents. And as the government seems to recognize (at 23-24, 31), a request for a preliminary injunction is appropriately adjudicated only when the biosimilar's launch is imminent. Neither Sandoz nor the government explains how a sponsor that does not receive marketing notice is supposed to determine when that point has arrived, without waiting until the biosimilar is licensed.

3. Sandoz's response to these grave implications is the unsubstantiated assertion (at 51) that "no rational applicant" would "'surprise' a sponsor by commercially marketing without notice ... in the face of potentially viable patents." That assumption is dubious. It is not uncommon for generic drug makers to "launch at risk"—that is, launch their products while patent claims remain pending. *E.g.*, O'Malley et al., *Failure to Launch*, Intell. Prop. Mag. 30, 30-32 (Apr. 2011) (noting several "at-risk" launches by generic companies between 2007 and 2011); *see also AstraZeneca AB* v. *Apotex Corp.*, 782 F.3d 1324, 1330, 1340-1341 (Fed. Cir. 2015) (setting forth damages rules that apply where pharmaceutical companies "launch their products ... knowing that they [are] at risk of later being held to infringe").

Even applicants that would not want to launch in the face of viable patents can easily miscalculate the risks, underestimating the strength of some of the sponsor's patents or failing to identify others. This case provides a good example. Sandoz claims (at 18) to have relied on a statement in Amgen's securities disclosures that its "material U.S. patents for filgrastim ... [had] expired." CAJA915, 960. But that was misguided. As Amgen had explained the previous year, only a composition-of-matter patent and a principal method-of-use patent for filgrastim were being referenced.[12] The disclosure did not purport to list every Amgen patent that could apply to the manufacture, use, or sale of biosimilar filgrastim products. Sandoz's speculative assump-

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[12] Amgen Inc., Annual Report (Form 10-K) at 4-5 (Feb. 27, 2013), *available at* https://www.sec.gov/Archives/edgar/data/318154/000144530513000364/amgn-12312012x10k.htm.

tions should therefore give the Court no confidence that construing §262(*l*) as optional will avoid chaos.

* * *

This Court sometimes must choose between an interpretation that most naturally reflects a statute's text and structure and one that better promotes the statute's purpose. Here, these indicia of statutory meaning point in the same direction. Congress enacted a detailed framework for the orderly resolution of patent disputes between biosimilar applicants and reference product sponsors. It repeatedly stated that applicants and sponsors "shall" carry out the steps in that framework. The structure of the statute, in which each step builds on its predecessors, depends on the parties' compliance. And when the parties comply, the result is an efficient resolution of patent disputes.

Instead of just following the framework Congress enacted, Sandoz asks the Court to hold that the entire framework is optional—the result of which would be a process so hopelessly disordered that Congress cannot have envisioned it. There is no reason for the Court to adopt that approach.

CONCLUSION

The Federal Circuit's judgment should be affirmed in part and reversed in part.

Respectfully submitted.

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MARCH 2017

APPENDIX

21 U.S.C. §355. New drugs

* * *

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c of this title. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in

consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

* * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

* * *

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

* * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect

to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

* * *

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

* * *

[5](B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

* * *

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certifi-

cation and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

* * *

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

* * *

[F](ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the ex-

piration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports

of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

* * *

28 U.S.C. §2201. Creation of a remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act.

35 U.S.C. §271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

* * *

[e](2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

* * *

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

* * *

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be grant-

ed by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

* * *

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(*l*)(4) of the Public Health Service Act or the lists of patents described in section 351(*l*)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(*l*)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(*l*)(3)(A) of the Public Health Service Act, including as provided under section 351(*l*)(7) of such Act for a biological product, but was not timely included in such list, may not bring an

action under this section for infringement of the patent with respect to the biological product.

* * *

42 U.S.C. §262. Regulation of biological products

* * *

(i) "Biological product" defined

In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product

may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

* * *

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biolog-

ical product continues to be safe, pure, and potent.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) Additional information

An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

* * *

(5) General rules

* * *

(C) Risk evaluation and mitigation strategies

The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) Exclusivity for first interchangeable biological product

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsec-

tion (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the

reference product was first licensed under subsection (a).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

* * *

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the

application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) In-house counsel

One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) Patent owner access

A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) Ownership of confidential information

The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any

publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application

has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor

would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall

be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be

the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (5)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference prod-

uct sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of pa-

tent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) Pediatric studies

* * *

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder

agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

* * *

RECORD AND BRIEFS

Supreme Court, U.S.
FILED
MAR 21 2016
OFFICE OF THE CLERK

No. 15-1039

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), *see* Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21, created a new regulatory pathway, 42 U.S.C. § 262(k), by which the FDA could approve a biologic product as "biosimilar to" a "reference product" that was itself approved under the full, traditional pathway of 42 U.S.C. § 262(a). "[B]alancing innovation and consumer interests," Pub. L. No. 111-148 § 7001(b), Congress established procedures to control and streamline patent litigation between the biosimilar applicant (the "Applicant") and the reference product sponsor (the "Sponsor" or "RPS"), *see* 42 U.S.C. § 262(*l*), triggered by the filing of an application under the new abbreviated pathway, *see id.* § 262(*l*)(1)(B)(i).

Sandoz Inc.'s petition for a writ of certiorari ("Sandoz's Petition") addresses part of those patent-litigation procedures, namely the requirement in subparagraph 262(*l*)(8)(A) that the Applicant provide 180 days' notice to the Sponsor before the first commercial marketing of the licensed biosimilar. Sandoz asks this Court to review this question:

> Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(*l*)(8)(A) as a stand-alone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper.

QUESTIONS PRESENTED (CONTINUED)

(Pet. at ii.)

Respondents Amgen Inc. and Amgen Manufacturing Limited (together, "Amgen") have today filed a Conditional Cross-Petition for a writ of certiorari to review an aspect of the Federal Circuit's decision that involves the same patent-dispute-resolution regime. Amgen's Cross-Petition presents this question:

> Is an Applicant required by 42 U.S.C. § 262(*l*)(2)(A) to provide the Sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the Applicant "shall provide," and, where an Applicant fails to provide that required information, is the Sponsor's sole recourse to commence a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii)?

(Cross-Pet. at i-iii.)

For the reasons set forth below, the Court should deny Sandoz's Petition. If the Court does so, it should deny Amgen's Cross-Petition too. If, however, the Court grants Sandoz's Petition, it should consider both questions regarding the patent-resolution scheme of the BPCIA by granting Amgen's Conditional Cross-Petition as well.

PARTIES TO THE PROCEEDINGS

The caption identifies all parties. Petitioner is Sandoz Inc. Respondents are Amgen Inc. and Amgen Manufacturing Limited.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondents Amgen Inc. and Amgen Manufacturing Limited state the following:

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with a 10% or greater ownership in Amgen Manufacturing Limited.

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BRIEF IN OPPOSITION

The Petition fails to satisfy the criteria for a grant of certiorari and should be denied.

This case is a poor vehicle for the Court's first interpretation of the BPCIA, for three reasons: First, the only part of Sandoz's question presented that is actually presented by this record is the part that the Federal Circuit decided unanimously, correctly holding that notice of commercial marketing is effective only if given after FDA licensure of the biosimilar product. Second, the rest of Sandoz's question presented, about the existence of a private right of action and the availability of injunctive relief, is moot on these facts, and the legal issues were not presented below. And third, the issues that are not ripe here are currently being litigated in the lower courts, including in a case in which the Federal Circuit will hear oral argument on April 4, 2016. This case is not an appropriate vehicle for this Court to decide these issues.

The Timing of Notice: The first half of Sandoz's question presented addresses whether notice of commercial marketing may be given before, or is effective only if given after, FDA licensure of the biosimilar product. The Federal Circuit correctly, and unanimously, decided that notice of commercial marketing is effective only if given after FDA licensure. The words of the statute are clear:

> Notice of commercial marketing. The subsection (k) applicant shall provide notice to the reference product sponsor not later

> than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

42 U.S.C. § 262(*l*)(8)(A) (emphasis added). Congress's use of the words "the biological product licensed under subsection (k)" was deliberate. In every other place in which subsection 262(*l*) refers to the proposed biosimilar product, it uses the phrase "the biological product that is the subject of" the subsection (k) application. *See, e.g.*, 42 U.S.C. § 262(*l*)(3)(A), (B), (C), (*l*)(7)(B). Here, and here only, the statute refers to "the biological product licensed under subsection (k)." That is because notice may be given only after the FDA has licensed (that is, approved) the biological product. Sandoz offers a raft of policy arguments for why this is supposedly a bad or unfair rule, arguments that are wrong on their merits but that in any event cannot overcome the statute's text. The Federal Circuit's decision is correct and not in conflict with the statute or any of this Court's decisions. This issue is therefore not appropriate for certiorari review.

Private Right of Action and Injunctive Relief: Sandoz argues that the Federal Circuit created an improper, extra-statutory remedy for an Applicant's failure to give timely notice, improperly created a private right of action to enforce subparagraph 262(*l*)(8)(A) where an Applicant does not provide timely notice of commercial marketing, and improperly "fashioned its own injunctive remedy" for that private right of action. (*E.g.*, Pet. at 19, 32.) But Sandoz provided timely notice after FDA

approval of its application, and thus this case does not present the question of what remedies would be available if an Applicant failed to do so. Moreover, Amgen did not sue on a private right of action to enforce the BPCIA; it brought established California state-law claims. (*See* Pet. App. at 63a-64a; D. Ct. Dkt. No. 1 (alleging causes of action for unfair competition under Cal. Bus. & Prof. Code § 17200 et seq. and conversion).) The district court expressly declined to reach whether there is a private right of action under the BPCIA because Amgen's state-law claims did not raise that issue. (*See* Pet. App. at 67a n.4.) After the district court denied Amgen's motion for a preliminary injunction, Amgen sought an injunction pending appeal pursuant to Fed. R. App. P. 8(a), based on the traditional four-factor test for equitable relief, and the Federal Circuit granted Amgen's motion. (*See* CAFC Dkt. No. 55 (Amgen's motion); CAFC Dkt. No. 83 (Sandoz's opposition); CAFC Dkt. No. 105 (order granting the motion).) The court's power came from the Federal Rules.

Cases Pending in the Lower Courts: The very issues in Sandoz's question presented that are not ripe here are currently percolating in the lower courts. To date there have been only seven lawsuits involving a biosimilar applicant's submission of an abbreviated biologics license application ("aBLA") to the FDA. All are still pending, and they present questions not only of underlying patent-law issues—whether a given product infringes a given patent, and the like—but also questions about how the BPCIA patent-litigation procedures are to be construed and applied. For example, on April 4,

2016, the Federal Circuit will hear oral argument in a case that presents one of the issues Sandoz wrongly asks this Court to decide here: whether a court has the power to issue a preliminary injunction where an Applicant refuses to provide notice of commercial marketing under subparagraph 262(*l*)(8)(A). *See Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. appeal docketed Dec. 11, 2015). That case also presents another question closely related to Sandoz's question presented here: The Federal Circuit will decide whether the obligation to give notice of commercial marketing under subparagraph 262(*l*)(8)(A) applies to only an Applicant that refused to give the Sponsor a copy of its biologics license application under subparagraph 262(*l*)(2)(A), as Sandoz did here, or whether that notice requirement also applies to an Applicant that complies with subparagraph 262(*l*)(2)(A), as Apotex did there. Two other pending cases address whether the Federal Circuit's decision in this case creates or implies a private right of action, an issue presented on the record of those cases but not on the record of this one. *See Amgen Inc. v. Hospira, Inc.*, No. 15-839 (D. Del. filed Sept. 18, 2015); *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-10698 (D. Mass. filed Mar. 6, 2015). The *Janssen* case also presents the related question of the impact of an Applicant's commencing the patent-litigation process called for by subsection 262(*l*) but then refusing to continue that process, as does another case between Amgen and Sandoz filed this month about a different proposed biosimilar product, *see Amgen Inc. v. Sandoz Inc.*, No. 16-01276 (D.N.J. filed Mar. 4, 2016).

Many of the components of the subsection 262(*l*) process are interlocking, and interpretation of one section can bear on many others. This Court should deny Sandoz's Petition and allow these issues to develop further, so that the Court's eventual review of these BPCIA provisions can be informed by the coming wave of district court and Federal Circuit decisions.

STATEMENT OF THE CASE

A. The Biologics Price Competition and Innovation Act of 2009

Sandoz's Petition suggests that the BPCIA was enacted to "create competition in the biologic pharmaceuticals market and to reduce prices." (Pet. at 2.) That tells only half of the story. Congress enacted the BPCIA in 2010 to establish "a biosimilars pathway balancing innovation and consumer interests." Pub. L. No. 111-148, § 7001(b) (emphasis added). Its goal is not just the regulation and licensure of potentially lower-cost biosimilar products, but also the protection of innovators' patent rights.

Before the BPCIA was enacted, the FDA could approve a biologics license application only under the full biologics pathway of 42 U.S.C. § 262(a), with its usual requirement of three phases of clinical trials to prove that "the biological product that is the subject of the application is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). An innovator of a new biological product was assured that, even apart from whatever patent protection it might have on that product, no other company could copy that

biological product and obtain FDA approval without first undergoing the expense of the 262(a) pathway. The innovator's investment to create a clinical trial data package to support and maintain FDA licensure of the innovator's biologic product was thereby protected from use by or for the benefit of would-be competitors.

The BPCIA changed that. Congress created a new biosimilars approval pathway, codified in 42 U.S.C. § 262(k) and commonly called "the (k) pathway." It allows the FDA to approve a biologic product that is "highly similar" to a "reference product" that was itself previously approved under the traditional subsection 262(a) pathway. *See id.* § 262(i)(2), (k)(3). Thus, while innovators previously enjoyed permanent and exclusive rights to their clinical trial data and FDA license, the BPCIA advanced the public's interest in price competition in part by diminishing these innovators' rights. It allowed an Applicant to "reference" the innovator's license, and to demonstrate that its proposed product is "highly similar" to the innovator's "reference product," *id.* § 262(i)(2), (k)(3), rather than incurring the costs of generating its own clinical data to demonstrate safety and efficacy. The BPCIA has no grandfather provision that would limit its applicability to only reference products licensed after the effective date of the legislation. *See id.* § 262(k).

On the other side of the balance, Congress protected the public's interest in innovation by establishing in subsection 262(*l*), "Patents," what the Federal Circuit aptly termed a "unique and elaborate process for information exchange between

the biosimilar applicant and the [Sponsor] to resolve patent disputes." (Pet. App. at 6a.) The process begins when the Applicant files an aBLA seeking review under the subsection (k) pathway. *See* 42 U.S.C. § 262(*l*)(1)(B)(i). Then, "[n]ot later than 20 days after" the FDA notifies the Applicant that its aBLA has been accepted for review, the Applicant "shall provide to the reference product sponsor a copy of the application submitted" to the FDA "under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). Subsection 262(*l*) further provides for an information exchange between the Sponsor and the Applicant, including identifying patents that might be infringed by the making, using, selling, offering for sale, or importation into the United States of the product that is the subject of the subsection (k) application, detailed infringement and invalidity contentions regarding those patents, and a discussion of licensure under some or all of those patents and whether the Applicant will await the expiry of some or all of those patents before marketing its product. *See* 42 U.S.C. § 262(*l*)(3)(A), (B), (C). If there remain patents in dispute, the Sponsor and Applicant work together to identify which of those patents will be included in an "Immediate patent infringement action" under paragraph 262(*l*)(6). *See id.* § 262(*l*)(4), (5), (6).

The elaborate process in subsection 262(*l*) also includes the notice-of-commercial-marketing provision at issue here, subparagraph 262(*l*)(8)(A). Textually, it is unlinked to any of the other

provisions of subsection 262(*l*). It states simply that, "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." It is, however, included within paragraph 262(*l*)(8), entitled "Notice of commercial marketing and preliminary injunction." Subparagraph 262(*l*)(8)(B) then provides that "[a]fter receiving the notice under subparagraph (A) and before the date of the first commercial marketing of such biological product," the Sponsor may seek a preliminary injunction under certain patents that were not listed for inclusion in the "immediate patent infringement action" under paragraph 262(*l*)(6). Subparagraph 262(*l*)(8)(C) then requires the Applicant and the Sponsor to cooperate reasonably to expedite discovery if the Sponsor seeks a preliminary injunction under subparagraph 262(*l*)(8)(B).

As described below, the first half of Sandoz's question presented asks whether the notice of commercial marketing under subparagraph 262(*l*)(8)(A) may be given <u>before</u> FDA approval of the Applicant's subsection (k) application or whether, as the Federal Circuit unanimously held, that notice is effective only if given <u>after</u> FDA approval.

B. Factual Background

1. Sandoz's aBLA and its Initial Notice of Commercial Marketing

Amgen discovered, developed, and markets NEUPOGEN® (filgrastim), a genetically engineered biologic protein that stimulates the production of neutrophils, a type of white blood cell. (*See* Pet. App. at 4a, 57a; D. Ct. Dkt. No. 1 at ¶¶ 45-47.) NEUPOGEN® is used, for example, to protect against a condition known as neutropenia, a potentially fatal neutrophil deficiency, induced in cancer patients by chemotherapy. (D. Ct. Dkt. No. 1 at ¶¶ 45-47.) The advent of NEUPOGEN® profoundly changed the treatment of many forms of cancer by greatly reducing deaths from neutropenia.

Sandoz filed an aBLA under the subsection (k) pathway seeking FDA approval of a biosimilar filgrastim product, designating Amgen's NEUPOGEN® as the reference product. (Pet. App. at 8a.) The FDA notified Sandoz it had accepted that aBLA on July 7, 2014. (*Id.*) Later in July, Sandoz informed Amgen that it would not provide Amgen with its aBLA or manufacturing information under subparagraph 42 U.S.C. § 262(*l*)(2)(A), and—purporting to satisfy the notice requirement of subparagraph 262(*l*)(8)(A)—informed Amgen that it would begin commercial marketing immediately upon FDA licensure. (Pet. App. at 8a-9a.) Sandoz said it expected to receive an FDA license some six to twelve months later, in the first half of 2015. (Pet. App. at 8a.)

2. District Court Proceedings, FDA Approval of Sandoz's aBLA, and Sandoz's Second Notice of Commercial Marketing

In October 2014, Amgen sued Sandoz in the Northern District of California, asserting claims of conversion, unlawful competition under California Business & Professions Code § 17200 et seq., and infringement of U.S. Patent 6,162,427. (Pet. App. at 9a.) Amgen alleged that Sandoz had competed unlawfully and converted the value of Amgen's license for NEUPOGEN® by referencing that license under the BPCIA while refusing to disclose its aBLA and manufacturing information to Amgen under subparagraph 262(*l*)(2)(A) and giving improper notice of commercial marketing under subparagraph § 262(*l*)(8)(A). (*See id.*) Sandoz counterclaimed for declaratory judgments that its reading of the BPCIA was correct. (*Id.*) Amgen sought a preliminary injunction, and the parties cross-moved for judgment on Amgen's state-law claims and Sandoz's counterclaims. (*Id.* at 9a-10a.)

While the motions were pending, on March 6, 2015 the FDA approved Sandoz's aBLA, licensing Sandoz to sell its biosimilar filgrastim product under the name ZARXIO®. (*Id.* at 8a-9a.) That same day, while maintaining that its July 2014 notice of commercial marketing had been operative, Sandoz gave Amgen a "further" notice of commercial marketing under subparagraph 262(*l*)(8)(A). (*Id.*)

On March 19, 2015, the district court granted partial judgment to Sandoz, holding that (i) despite the use of the words "shall provide," the BPCIA allows an Applicant to refuse to provide its aBLA

and manufacturing information; (ii) where an Applicant refuses to provide that information, the Sponsor may not obtain injunctive relief, restitution, or damages for that refusal, and is instead limited to seeking a declaratory judgment under subparagraph § 262(*l*)(9)(C); and, (iii) the Applicant may give notice of commercial marketing under subparagraph 262(*l*)(8)(A) before FDA approval, and thus that Sandoz's July 2014 notice was timely. The district court entered judgment against Amgen on its state-law claims, and denied its motion for a preliminary injunction. (*Id.* at 10a.) Proceedings on Amgen's patent claim were stayed, and Amgen timely appealed to the Federal Circuit. (*Id.* at 11a.)

3. The Federal Circuit Decision

Amgen sought an injunction pending appeal under Fed. R. App. P. 8(a) and the traditional four factors of the equitable test for such an injunction: likelihood of success on the merits, irreparable harm, a balance of hardships favoring the movant, and the public interest. (*See* CAFC Dkt. No. 55.) Over Sandoz's opposition (*see* CAFC Dkt. No. 83), the Federal Circuit entered an injunction pending appeal on May 5, 2015, enjoining Sandoz from marketing, selling, or offering for sale its ZARXIO® product until the court resolved the appeal. (*see* CAFC Dkt. No. 105).

On July 21, 2015, the Federal Circuit issued its decision on Amgen's appeal. (*See* Pet. App. 1a-55a.) The panel comprised Judges Lourie, Newman, and Chen, with Judge Lourie writing the majority opinion, joined in various parts by Judge Newman, Judge Chen, or both. (*See id.*)

Judge Lourie, joined by Judge Chen, held that while subparagraph (*l*)(2)(A) says that the Applicant "shall provide" a copy of its aBLA and related manufacturing information to the Sponsor, that requirement is not actually mandatory, and where an Applicant refuses to provide that information the Sponsor's only recourse is to commence a patent-infringement suit under 35 U.S.C. § 271(e)(2)(C)(ii) or a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and obtain that information through discovery. (*See id.* at 12a-18a.) From this, Judge Newman dissented. (*See id.* at 32a-42a.)

Turning to the notice of commercial marketing under subparagraph 262(*l*)(8)(A), the Federal Circuit held, unanimously, that such notice is effective only if given after the FDA licenses the product under subsection (k). (*Id.* at 18a-22a.) The court based this conclusion on the language of subparagraph 262(*l*)(8)(A) itself, on Congress's use of different language in other parts of the BPCIA, and on the purpose of a post-approval 180-day notice period, which allows a "defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product" and "ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." (*Id.* at 21a.)

The Federal Circuit then considered Sandoz's argument, pressed in that court, that the "shall" language of subparagraph 262(*l*)(8)(A) is not mandatory and that an Applicant does not need to provide notice at all. Judge Lourie, joined by Judge Newman, held that an Applicant must give notice of commercial marketing under subparagraph

262(*l*)(8)(A). (Pet. App. at 23a-26a.) Deeming Sandoz's March 6, 2015 notice of commercial marketing, given after FDA approval, to have been "operative and effective," (*id.* at 23a), the majority held that "Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.,* September 2, 2015," (*id.* at 26a), and extended the injunction pending appeal to only September 2, 2015, (*id.* at 26a, 31a). Judge Chen dissented from these parts of the panel decision. (*See id.* at 42a-55a.)

Each of Sandoz and Amgen petitioned for en banc review, with Sandoz challenging aspects of the panel's decision regarding notice of commercial marketing under subparagraph 262(*l*)(8)(A) and Amgen challenging the panel's decision regarding the Applicant's obligation to give the Sponsor a copy of its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A). (*See* CAFC Dkt. Nos. 118 & 119.) Both petitions for en banc review were denied without further opinion. (Pet. App. at 85a-86a.) Amgen sought to extend the injunction pending appeal while en banc proceedings continued (CAFC Dkt. No. 124), and that application, too, was denied. (CAFC Dkt. No. 128.) Sandoz began commercial sales of its ZARXIO® product on September 3, 2015. (Pet. at 20.)

4. Proceedings in This Court

Sandoz filed a petition for a writ of certiorari, No. 15-1039, on February 16, 2016, which was docketed on February 18, 2016.

Sandoz's Petition challenges two aspects of the Federal Circuit's decision: (1) the unanimous

holding that the notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) is effective only if given after FDA approval of the biosimilar, and not before; and (2) the extension of the injunction pending appeal through September 2, 2015, which was 180 days after Sandoz's March 6, 2015 notice of commercial marketing.

For the reasons set forth herein, Amgen respectfully submits that the Court should deny Sandoz's Petition.

Concurrently with this brief in opposition, Amgen is filing a Conditional Cross-Petition, addressing the Federal Circuit's decision that the language in subparagraph 262(*l*)(2)(A) that the Applicant "shall provide" the Sponsor with a copy of its aBLA and manufacturing information is not mandatory, and that where an Applicant refuses to provide that information the Sponsor's only recourse is to commence a patent-infringement suit under 35 U.S.C. § 271(e)(2)(C)(ii) or a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and obtain that information through discovery.

If the Court denies Sandoz's Petition, it should deny Amgen's Cross-Petition as well. If the Court grants Sandoz's Petition, however, then it should grant Amgen's Cross-Petition too, and should consider the correct interpretation of the BPCIA provisions together, rather than interpreting each provision of the statute separately.

REASONS FOR DENYING THE PETITION

While this Court has not yet interpreted the BPCIA, this case is a poor vehicle for the Court to first interpret that statute. Sandoz's question presented raises two issues, only one of which is actually presented by the factual and legal record below. That portion, the first half of Sandoz's question presented, is about the timing of effective notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A). The Federal Circuit unanimously and correctly held that notice is effective only if given after FDA approval, a conclusion consistent with the statutory text and not in conflict with any decision of this Court. (*See* Pet. App. at 22a.) The rest of Sandoz's question presented addresses the existence of a private right of action and the availability of injunctive relief, issues that are moot on these facts and that are not presented by the record. Moreover, to the extent that those issues might be worthy of this Court's review at some point, they are currently being litigated in the lower courts. One of those cases might someday be an appropriate vehicle for this Court's review; this case is not such a vehicle.

I. THE FEDERAL CIRCUIT'S RESOLUTION OF THE FIRST HALF OF SANDOZ'S QUESTION PRESENTED DOES NOT CONFLICT WITH ANY DECISION OF THIS COURT OR THE STATUTORY TEXT

The first half of Sandoz's question presented is "Whether notice of commercial marketing given before FDA approval can be effective" under subparagraph 262(*l*)(8)(A). (Pet. at ii.) The Federal

Circuit answered this unanimously, holding that notice of commercial marketing is effective only if given after FDA licensure of the Applicant's product under subsection (k). (Pet. App. at 22a.) That decision was correct, was consistent with the statutory text and purpose, and does not conflict with any decision of this Court. There is no reason to grant Sandoz's Petition to hear this issue.

The Federal Circuit began its analysis, as this Court requires in "all statutory construction cases," with "the language of the statute." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002). The "first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case," *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997), with the question of ambiguity "determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole," *id.* at 341.

That is exactly what the Federal Circuit did here. It began with the text of subparagraph (*l*)(8)(A):

> Paragraph (*l*)(8)(A) provides that "[t]he subsection (k) applicant *shall* provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k).'

(Pet. App. 18a-19a (emphases in opinion).) A product is "licensed" only after the FDA approves the application. Sandoz now twice refers to

"licensed" as an "adjective," asserting that the word "just identifies the product whose commercial marketing is relevant." (Pet. at 24; *see also id.* at 6.) The words "licensed under subsection (k)" do indeed identify the product, but "licensed" is the past tense of a verb; its use signifies that the Applicant needs to give notice once the product has been licensed. It is only after the aBLA is approved that the product becomes a "product licensed under subsection (k)." "Licensed" means "[t]o whom or for which a licence has been granted; provided with a licence." 1 Oxford English Dictionary 245 (Oxford Univ. Press, Compact ed. 1971).

As the Federal Circuit concluded, consistent with *Robinson*, this is confirmed by the context in which that language is used. (*See* Pet. App. at 20a.) Subparagraph 262(*l*)(8)(A) is the only place in subsection 262(*l*) where Congress used the phrase "the biological product licensed under subsection (k)." In every other place where subsection 262(*l*) refers to the product, Congress used the words "the biological product that is the subject of" the subsection (k) application. *See* 42 U.S.C. § 262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B).

The Federal Circuit faithfully applied this Court's precedents that where Congress uses two different terms or phrases it is assumed to intend different meanings. (*See* Pet. App. at 20a-21a (citing *Russello v. United States*, 464 U.S. 16, 23 (1983)).) Where Congress referred to acts occurring prior to the licensure of the product, it used the phrase "the biological product that is the subject of" the

subsection (k) application. Elsewhere in the BPCIA, where Congress used phrase "product licensed" it did so in provisions unambiguously referring to products that have already been approved by the FDA. Thus, subsection 262(d) refers to the post-approval recall from the market of a "product licensed." And paragraph 262(i)(4) defines the term "reference product" to refer to the "biological product licensed under subsection (a) against which" the proposed biosimilar product is evaluated.

Given Congress's use of these phrases, the Federal Circuit correctly concluded that the use of the phrase "product licensed" in subparagraph 262(*l*)(8)(A) meant that effective notice of commercial marketing could be given only after the FDA has approved the Applicant's aBLA and there is thus a "product licensed."

That conclusion is also supported by other provisions of the BPCIA that suggest that FDA approval and commercial marketing will occur some six months apart. Thus, paragraph 262(k)(6) affords a period of market exclusivity for the first biosimilar that demonstrates "interchangeability" with respect to the reference product. *See* 42 U.S.C. § 262(k)(2)(B), (k)(4), (k)(6). During that period, the FDA may not approve the application for any other biosimilar claiming similarity to the same reference product. Paragraph 262(k)(6) provides that the exclusivity period ends with the first to occur of five events. Notable here is the fact that one of them is one year after the first commercial marketing of the interchangeable biosimilar, while another is eighteen months after the approval of that biosimilar, suggesting that first commercial

marketing will not occur on the heels of FDA approval, but rather will follow that approval by some 180 days. *Compare* 42 U.S.C. § 262(k)(6)(A), *with id.* § 262(k)(6)(C)(ii).

Further, the contrary reading Sandoz proposes—that notice of commercial marketing may be given as soon as the Applicant files its aBLA—would render other statutory provisions unworkable. For example, subparagraph 262(*l*)(9)(A) refers to a period that begins when the Applicant provides the Sponsor with a copy of its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A), which it is to do within 20 days of being notified that the FDA has accepted that application for review, and that ends when the Applicant gives the notice of commercial marketing under subparagraph 262(*l*)(8)(A). If Sandoz were correct and an Applicant could give notice of commercial marketing as soon as it files its aBLA, the period in subparagraph 262(*l*)(9)(A) would end before it even began, rendering it meaningless. As another example, subparagraph 262(*l*)(8)(B) contemplates the Sponsor moving for a preliminary injunction during the 180-day period on patents that were identified in the paragraph 262(*l*)(3) exchanges, but that were not listed for inclusion in the immediate patent-infringement action under paragraph 262(*l*)(6) or that were later identified in accordance with paragraph 262(*l*)(7). If Sandoz were correct that the notice of commercial marketing could be given as soon as an Applicant files its aBLA, the 180-day period could elapse before the patent exchanges have been completed and before the

patents referred to in subparagraph 262(*l*)(8)(B) can even be identified.

For all of these reasons, the statutory text and context of subparagraph 262(*l*)(8)(A) make clear that notice of commercial marketing may be given only after FDA approval of the subsection (k) application—that is, when the product is licensed. But the Federal Circuit also considered, as required by *Robinson*, the broader context of the statute as a whole. 519 U.S. at 340. The court noted that when an Applicant "files its aBLA, it likely does not know for certain when, or if, it will obtain FDA licensure. The FDA could request changes to the product during the review process, or it could approve some but not all sought-for uses." (Pet. App. at 21a.) The possibility of changes in the product or its uses suggests that Congress would have intended the notice of commercial marketing and its 180-day period to follow FDA approval. "Giving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court." (*Id.*)

Consider the implications of Sandoz's contrary proposal. An Applicant would file its aBLA on a product that might never be approved, seeking approval for indications that it might never obtain. The Sponsor would have to seek a preliminary injunction to prevent the sale of a product which may not happen for years, or ever. The courts would face entirely unnecessary applications for injunctive relief, and presumably would deny some or all of

them as not being ripe. On the other hand, as the Federal Circuit held, requiring that notice of commercial marketing be given only after FDA approval ensures a 180-day period in which preliminary injunctions can be sought based on the actual facts that matter—*i.e.*, the right and scope of permissible manufacture, marketing, and sale, and the approved therapeutic use or uses, all of which are defined by the FDA license:

> Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product.

(*Id.*) In contrast, if the notice of commercial marketing "could be given at any time before FDA licensure, the RPS would be left to guess the scope of the approved license and when commercial marketing would actually begin." (*Id.*)

The Federal Circuit's decision is thus consistent with the text of the provision at issue and with the surrounding context and the statute as a whole. In asking this Court to review that decision, Sandoz predominantly makes policy arguments for why it would prefer a different rule. None of those is a reason to grant the writ of certiorari.

Sandoz first gamely tries a textual argument, observing that the notice of commercial marketing is to be given by "the subsection (k) *applicant*" and

arguing that once the FDA approves the application that entity is no longer an "applicant" but a license "holder." (Pet. at 25 (adding emphasis to statutory language).) But Sandoz omits that "subsection (k) applicant" is a defined term in subsection 262(*l*), defined to refer to "a person that submits an application under subsection (k)." 42 U.S.C. § 262(*l*)(1)(A). Thus, Sandoz remains the "subsection (k) applicant" even after FDA approval of ZARXIO®; it is the person that submitted the application under subsection (k). The use of that defined term in subparagraph 262(*l*)(8)(A) says nothing about the timing of the notice obligation. It identifies who must give the notice: the Applicant.

Then Sandoz argues that requiring an Applicant to give notice after approval "makes little sense" because FDA approval is a public act so the Sponsor does not need notice from the Applicant. (Pet. at 25.) Notice "after FDA approval would be superfluous." (*Id.* at 6.) That misstates the purpose of notice. The Applicant gives notice so that the Sponsor will know <u>when</u> the Applicant will commence marketing of the now-approved product, giving the Sponsor at least 180 days to seek a preliminary injunction. It cannot be presumed that commercial marketing will always follow 180 days after approval: an Applicant might delay commercial marketing after licensure to await trial on the merits of a paragraph 262(*l*)(6) patent litigation, for commercial reasons, for supply reasons, or even to wait for the expiration of a patent. If first commercial marketing is not imminent upon licensure, the BPCIA should not be

interpreted to burden the court with an unnecessary (and perhaps not ripe) application for an injunction.

Finally, Sandoz argues that requiring 180 days between approval and commercial marketing results in an extra period of "market exclusivity" for the Sponsor beyond the 12 years provided for by paragraph 262(k)(7). (Pet. at 4; *see also id.* at 27-31.) It does not. The BPCIA does not confer any market exclusivity on a Sponsor. Market exclusivity is a period during which only the original innovative product may be on the market, ensuring a lack of competition. It "prevents a competing firm from obtaining FDA approval whether or not it has generated its own safety and efficacy data." John R. Thomas, Cong. Research Serv., *The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation* 4 (Jan. 15, 2014) (internal citations omitted) [hereinafter, "Thomas, *The Role of Patents*"]. There is no market exclusivity conferred by the BPCIA. Another company is free to generate its own clinical efficacy and safety data and to pursue its own approval of the same biologic product under the traditional approval pathway of subsection 262(a) at any time. Indeed, Teva did just that, obtaining approval on August 29, 2012 of its own filgrastim product, GRANIX®, under subsection 262(a). *See* U.S. Food & Drug Admin., *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations* (Feb. 26, 2016), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm.

What the BPCIA confers is not market exclusivity, then, but twelve years of data exclusivity. "Data exclusivity protects the safety and efficacy information—often termed the 'data package'—submitted by the brand-name firm from use by generic firms. As a result, a generic firm may not rely upon that data in support of its own application for FDA marketing approval for a period of years." Thomas, *The Role of Patents* at 4. Thus, under the BPCIA, the FDA may not approve a biosimilar application under the abbreviated pathway of subsection (k) until "the date that is 12 years after the date on which the reference product was first licensed under subsection (a)." 42 U.S.C. § 262(k)(7)(A). Whereas before the BPCIA biologics innovators enjoyed permanent data exclusivity, the BPCIA reduced that period to only twelve years.

None of this has anything to do, however, with the 180-day period under subparagraph 262(*l*)(8)(A). That provision affords no "exclusivity" at all. Take, for example, the product here: filgrastim. During the 180 days after the FDA approved Sandoz's ZARXIO® product, there was already a competing filgrastim product in the market: Teva's GRANIX® product. And Apotex has announced that it filed an aBLA seeking approval of its own biosimilar filgrastim product listing Amgen's NEUPOGEN® as the reference product. *See Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. appeal docketed Dec. 11, 2015). If the FDA approves Apotex's application someday, and Apotex has to then give 180 days' notice before beginning commercial marketing, Amgen will not enjoy any exclusivity during that period. Both Teva's GRANIX® and Sandoz's

ZARXIO® will be in the market, competing with Amgen's NEUPOGEN®.

What subparagraph 262(*l*)(8)(A) affords is not exclusivity, but notice and a time during which the Sponsor can seek, and the courts can efficiently address, a preliminary injunction application. In holding that the notice called for by that subparagraph is effective only if given after FDA approval, the Federal Circuit faithfully applied this Court's statutory-interpretation precedents, faithfully applied the text of the BPCIA, and did so consistently with the statutory context. There is no reason for this Court to grant a writ of certiorari to review that decision.

II. THE SECOND HALF OF SANDOZ'S QUESTION PRESENTED IS NOT ACTUALLY PRESENTED BY THE RECORD OF THIS CASE

The second half of Sandoz's question presented is whether "'treating Section 262(*l*)(8)(A) as a standalone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper." (Pet. at ii.) Sandoz argues that the Federal Circuit "disregarded the remedies provided by the BPCIA and instead created its own extra-textual remedy to enforce its interpretation: a private right of action for an automatic injunction." (Pet. at 31.) Sandoz accuses the Federal Circuit of thus running afoul of this Court's instruction that the courts "are not free to fashion their own remedies" and of this Court's instruction that injunctions may not issue in patent cases without satisfying the traditional equitable injunctive test.

(*Id.* at 31 (*citing Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001)) and 36 (citing *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392-93 (2006)).)

None of the principles invoked by Sandoz applies to this case. The Federal Circuit did not disregard "the remedies" in the BPCIA for a failure to give notice under subparagraph 262(*l*)(8)(A); Sandoz gave notice under that provision. Its doing so moots any question of what remedies might or might not exist if had not done so. Moreover, Amgen did not sue on an implied private right of action in this case; it brought established remedies under California state-law. And the Federal Circuit did not fashion a new injunctive remedy; it granted an injunction pending appeal pursuant to Fed. R. App. P. 8(a) under the traditional test in equity. Thus, there is no reason for this Court to grant a writ of certiorari to review the second half of Sandoz's question presented, because that half is not actually presented on this record.

1. The "Remedies" Under the BPCIA. Sandoz discusses, at some length, the provisions of the BPCIA that address an Applicant's failure to provide notice of commercial marketing under subparagraph 262(*l*)(8)(A). (*See* Pet. at 34-36.) It focuses on subparagraph 262(*l*)(9)(B), which details how the limitations on actions for declaratory judgment with respect to certain patents are to be applied by the courts. Paragraph (*l*)(9) is entitled "Limitation on declaratory judgment action." Subparagraph (*l*)(9)(A) prohibits both the Applicant and the Sponsor from commencing declaratory-judgment actions until the time that the Applicant

gives notice of commercial marketing under subparagraph 262(*l*)(8)(A), after having provided a copy of its aBLA and manufacturing information in accordance with subparagraph 262(*l*)(2)(A). *See* 42 U.S.C. § 262(*l*)(9)(A). The next subparagraph, on which Sandoz focuses, continues the prohibition on declaratory judgments by the Applicant where, among other things, the Applicant "fails to complete" the action required of it by subparagraph 262(*l*)(8)(A). *See id.* § 262(*l*)(9)(B).

Sandoz now argues that a declaratory judgment under subparagraph 262(*l*)(9)(B) is the exclusive remedy available to a Sponsor where an Applicant fails to give timely notice of commercial marketing under subparagraph 262(*l*)(8)(A), and thus that the courts do not have the power to enjoin commercial marketing by an Applicant that refuses to give timely notice.

That issue is not presented on this record. Sandoz gave timely notice on the day that the FDA approved its aBLA, March 6, 2015. (Pet. App. at 8a-9a.) In doing so, it satisfied subparagraph 262(*l*)(8)(A), as the Federal Circuit held. (*See id.* at 23a.) This case thus does not raise the question of what remedies might have been available to Amgen had Sandoz not given notice. As discussed below in Point III, however, that question is presented in the case in which the Federal Circuit will hear oral argument on April 4, 2016, in which Apotex has refused to provide notice of commercial marketing. Even if this is an issue that may someday warrant this Court's review after it has been presented in and decided by the lower courts, this is not an appropriate case in which to review that issue now.

The Court should wait for a case in which the facts present the legal question.

2. Private Right of Action. Nor is this an appropriate vehicle for this Court to determine whether there is a private right of action under the BPCIA. We begin with the pleadings: Amgen sued Sandoz in relevant part under two California state-law claims, one for conversion and one for unlawful competition under California Business & Professions Code § 17200 et seq. (*See id.* at 9a.) Amgen did not assert a private right of action under the BPCIA. Indeed, when Amgen suggested at oral argument that a private right of action might also support relief, the district court found that Amgen had not brought such a claim, that the issue was "not properly raise[d]" by the motions, and "accordingly," that it "will not be addressed." (Pet. App. at 67a.)

The Federal Circuit majority discussed notice of commercial marketing in the context of Amgen's Section 17200 claim. When Amgen filed that claim in October of 2014, Sandoz had not yet received FDA approval and it was not then clear whether Sandoz would give notice of commercial marketing upon receiving that approval. (*See* Pet. App. at 8a-9a.) At that time, Sandoz was still contending that its July 2014 notice was effective. (*See id.*) Because Sandoz ultimately gave effective notice after FDA approval, the Federal Circuit majority held that Amgen's Section 17200 claim became moot:

> As indicated, under our interpretation of the BPCIA, the July 2014 notice is ineffective, and Sandoz gave the operative notice on

> March 6, 2015. Thus, as we have indicated, Sandoz may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015. And, as indicated below, we will extend the injunction pending appeal through September 2, 2015. Amgen's appeal from the dismissal of its unfair competition claim based on the alleged violation of § 262(*l*)(8)(A) is therefore moot.

(*Id.* at 27a-28a.)

As discussed further in Point III below, the existence of a private right of action under the BPCIA is being litigated in two other pending BPCIA cases. *See Amgen Inc. v. Hospira, Inc.*, No. 15-839 (D. Del. Nov. 6, 2015); *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-10698 (D. Mass. filed Mar. 6, 2015). Indeed, Amgen has argued in the case against Hospira that there is a private right of action under the BPCIA. Whether the decision below supports such a private right of action will need to be determined in a subsequent case. On the record of this case, Amgen did not assert an implied private right of action, but proceeded instead on California state-law claims. (*See* Pet. App. at 63a-64a.)

3. Extra-Statutory Injunction. There is also no basis for this Court to review the Federal Circuit's "extra-statutory" injunction or a violation of *eBay*, because the Federal Circuit did not issue an extra-statutory injunction or violate *eBay*.

The Federal Circuit issued an injunction pending appeal under Fed. R. App. P. 8(a). Amgen sought

that injunction by showing that it was likely to succeed on the merits, that it faced irreparable harm, that the balance of hardships favored an injunction, and that an injunction was in the public interest. (*See* CAFC Dkt. No. 55.) Sandoz opposed entry of that injunction by arguing about those very factors. (*See* CAFC Dkt. No. 83.) Sandoz lost, Amgen won, and the Federal Circuit exercised the injunctive power granted it by the Federal Rules of Appellate Procedure. (*See* CAFC Dkt. No. 105.)

Then, when the Federal Circuit issued its decision, it shortened that injunction pending appeal until only September 2, 2015, which is 180 days after the notice of commercial marketing that Sandoz gave on March 6, 2015. (Pet. App. at 27a-28a.) When Sandoz gave notice on March 6th, September 3, 2015 became the soonest Sandoz could begin commercial marketing. Sandoz's counsel was clear on this point at oral argument: "Sandoz re-gave notice on the day of approval, and . . . six months from that would be September 2nd. That would be the outside date that any injunction against marketing could apply." Oral Argument at 35:41, *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1499.mp3.

Thus, the Federal Circuit "enjoined" Sandoz from doing something it had committed not to do anyway: begin commercial marketing before September 2, 2015. Sandoz has never contended—in the district court, in the Federal Circuit, or in this Court—that an Applicant may give 180 days' notice of commercial marketing but then disregard that notice and begin marketing in fewer than 180 days.

All that Sandoz was enjoined from doing, then, is what it had already promised not to do. When Amgen sought to extend the injunction beyond September 2, 2015 in connection with proceedings en banc, the Federal Circuit denied Amgen's request. (CAFC Dkt. No. 128.) Sandoz began marketing ZARXIO® on September 3, 2015. (Pet. at 20.)

Importantly, as described below in Point III, the Federal Circuit will shortly hear argument in a case that does raise the question of a court's power to issue an injunction where the Applicant refuses to provide notice of commercial marketing, the *Amgen Inc. v. Apotex Inc.* case, to be argued on April 4, 2016.

That case, or some subsequent case, might present issues worthy of this Court's review. But none of the issues inherent in the second half of Sandoz's question presented is actually presented by the record of this case, and thus this Court should deny Sandoz's request for a writ of certiorari.

III. THIS CASE IS A POOR VEHICLE FOR REVIEW NOW BECAUSE THESE ISSUES ARE STILL BEING DEVELOPED IN ACTIVE LOWER-COURT CASES

There is no dispute that the BPCIA is an important new statute, and that its proper interpretation is an issue of great importance to innovative biopharmaceutical companies, to those who would propose to make biosimilar versions of those innovators' products, and to the public. But

what matters here is not that the statute is important, but that it is new.

There have been only seven lawsuits involving a biosimilar applicant's submission of an aBLA to the FDA, with the most recent of them (also between Amgen and Sandoz) having been filed just this month. All seven lawsuits are still pending. And each raises issues about the proper interpretation of the patent-litigation provisions in subsection 262(*l*).

"Often, a denial of certiorari on a novel issue will permit the state and federal courts to 'serve as laboratories in which the issue receives further study before it is addressed by this Court.'" *Lackey v. Texas*, 514 U.S. 1045, 1047 (1995) (Stevens, J., respecting denial of certiorari) (quoting *McCray v. New York*, 461 U.S. 961, 963 (1983)). "Disagreement in the lower courts facilitates percolation—the independent evaluation of a legal issue by different courts." *California v. Carney*, 471 U.S. 386, 401 n.11 (1985) (Stevens, J., dissenting). Because the BPCIA is an "Act of Congress relating to patents," the Federal Circuit's jurisdiction is exclusive in actions arising under the BPCIA. 28 U.S.C. § 1295(a)(1). While there cannot be a split in the circuit courts here, however, there can and will be differences in decision among the district courts, and opportunities for the Federal Circuit to resolve those differences. As part of this process, other judges of the Federal Circuit, beyond the single panel that has spoken so far, will articulate their views on the interpretation of the statute.

This Court should wait to take a BPCIA case until the law has evolved further. That is

particularly true here because, as set forth above in Point I, the only issue in Sandoz's question presented that is actually presented by this case—the timing of effective notice of commercial marketing under subparagraph 262(*l*)(8)(A)—was decided by a unanimous Federal Circuit consistently with the statutory text and this Court's precedents, and because the other components of Sandoz's question presented, while not presented here, are being decided in pending lower-court cases.

Most imminently, and as alluded to above, the Federal Circuit will hear oral argument on April 4, 2016 in a case about notice of commercial marketing under subparagraph 262(*l*)(8)(A). *See Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. appeal docketed Dec. 11, 2015). There, Apotex announced that it will not provide notice even if the FDA approves its application, so Amgen sought and obtained a preliminary injunction prohibiting Apotex from commercial marketing until it (a) receives FDA approval, (b) then gives notice under subparagraph 262(*l*)(8)(A), and (c) waits at least 180 days after giving that notice. *See id.* The Federal Circuit will decide whether such an injunction is appropriate. And the Federal Circuit will consider whether the requirement to give notice of commercial marketing applies only where an Applicant (like Sandoz, but not like Apotex) refuses to give the Sponsor a copy of its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A), or whether it applies to all Applicants.

Other pending cases present the other issues Sandoz now asks this Court to reach precipitously. For example, the dispute between Janssen Biotech

and Celltrion pending in Massachusetts raises the question of the interplay between subparagraphs 262(*l*)(2)(A) and 262(*l*)(8)(A) and whether there is a private right of action to enforce the notice of commercial marketing provision in subparagraph 262(*l*)(8)(A). *See Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-10698 (D. Mass. filed Mar. 6, 2015). The parties' summary judgment motions on those issues are before the district court now. *See, e.g.*, *Janssen*, No. 15-10698 (D. Mass. Feb. 17, 2015) (Janssen's memorandum). The case between Amgen and Hospira also raises the question of whether a private right of action exists under subparagraph (*l*)(8)(A), with Amgen arguing that it does. Hospira's motion to dismiss, addressed to the existence of a private right of action, is pending. *See Amgen Inc. v. Hospira, Inc.*, No. 15-839 (D. Del. Oct. 13, 2015). And a case between Amgen and Sandoz that was filed just this month addresses whether an Applicant, after receiving the Sponsor's list of potentially applicable patents under subparagraph 262(*l*)(3)(A) may then unilaterally terminate the process called for by subparagraphs 262(*l*)(3)(C) through (*l*)(5), provisions that all use the "shall" language in the provisions at issue here. *See Amgen Inc. v. Sandoz Inc.*, No. 16-01276 (D.N.J. filed Mar. 4, 2016).

This Court and the public would benefit from allowing these pending cases to be resolved by the lower courts. The Federal Circuit expedited proceedings in this case and issued its decision less than two months after oral argument. If it follows the same pace in, for example, the *Apotex* case, a decision would likely issue sometime in May or

June. That decision would almost certainly issue before this Court begins its October 2016 Term, and will bear directly on the issues presented here.

While that is a sufficient reason for this Court to deny Sandoz's Petition and allow further, lower-court percolation of these issues, there are other reasons too.

First, there is little factual urgency here. Unlike Abbreviated New Drug Applications under the Hatch-Waxman Act[1] of which the FDA has already approved fourteen in 2016 alone, *see* U.S. Food & Drug Admin., *ANDA (Generic) Drug Approvals*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ (last visited Mar. 21, 2016), there have been seven biosimilar applications submitted as of September 30, 2015, and the FDA thus far has approved only one aBLA under the subsection (k) pathway, Sandoz's application for ZARXIO®. *See* E. Research Grp., Inc., *Review of Biosimilar Biologic Product Applications* at ES-2 (Feb. 24, 2016), http://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM488846.pdf. Thus, while this case presents the question of whether notice of commercial marketing must follow FDA approval, this is not a circumstance in which that issue will actively bear on dozens of pending applications.

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[1] Drug and Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355, 28 U.S.C. § 2201, and 35 U.S.C. §§ 156, 271, & 282).

Second, while Sandoz's Petition frames the issue as an urgent need to put low-cost medications in the hands of prescribers and patients, the need is not urgent and the cost is not meaningfully lower. It is not urgent because thus far ZARXIO® is the only approved biosimilar in America. And Sandoz is pricing ZARXIO® at only a 15% discount from Amgen's wholesale price, a far cry from the much greater price reductions—as high as 80 to 85%—typically seen with generic drugs in the small-molecule market under the Hatch-Waxman Act. *See* Fitch: Gradual Conversion Begins as First Biosimilar Hits US Market, Business Wire, (Sept. 16, 2015), http://www.businesswire.com/news/home/20150916006137/en/Fitch-Gradual-Conversion-Begins-Biosimilar-Hits-Market#.Vfrzj526dbW; Food & Drug Admin., *Facts about Generic Drugs*, http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm (last visited Mar. 21, 2016).

The impact on consumer costs from this Court waiting for the issues to develop further in the lower courts and at the FDA would be minimal, while the benefit to the Court of further developments in the law would be significant.

CONCLUSION

For the foregoing reasons, Sandoz's Petition should be denied.

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MARCH 21, 2016

RECORD AND BRIEFS

No. 15-1039

FILED
MAY 31 2016
OFFICE OF THE CLERK

In The

Supreme Court of the United States

SANDOZ INC., PETITIONER,

v.

AMGEN INC. AND
AMGEN MANUFACTURING LIMITED.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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INTRODUCTION

Until this Court intervenes, the Federal Circuit's decision will delay patient access to every biosimilar for at least six months after the biosimilar has been approved by the Food and Drug Administration ("FDA"). Amgen does not deny that is the effect of the Federal Circuit's ruling. Under the court of appeals' erroneous interpretation of 42 U.S.C. § 262(*l*)(8)(A), a biosimilar applicant cannot provide notice of commercial marketing until *after* FDA approval—and a reference product sponsor can obtain a federal injunction barring commercial marketing until 180 days after that notice.

Too much is at stake to accede to Amgen's plea to postpone review. The length of the twelve-year exclusivity period in the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") was a hard-fought compromise. By adding six more months of extra-statutory exclusivity, the Federal Circuit has disrupted the balance struck by Congress. This case presents the only foreseeable vehicle to restore that balance. Amgen points to no other case likely to present the question whether the notice of commercial marketing can be given before FDA approval. Nor is there one: as Amgen does not dispute, the Federal Circuit's ruling on this issue binds the nation.

And that ruling is wrong. The plain text of the statute provides that *marketing* must await FDA approval, not that the *notice* of marketing must do so. The

Federal Circuit compounded its erroneous interpretation by turning the BPCIA's mere notice provision into a federal right of action for an automatic 180-day injunction against marketing. While Amgen questions whether the Federal Circuit created such a right, that is the only possible explanation for the court's injunction—in fact, the court held Amgen's state law claim moot because it already had determined to grant an injunction directly under the BPCIA.

ARGUMENT

A. The Questions Presented By Sandoz's Petition Are Important And Warrant This Court's Review Now

This Court's intervention is urgently needed because the Federal Circuit's ruling will necessarily delay the market entry of *every* approved biosimilar, thus thwarting Congress's goal of making less-expensive biologics available to patients and payors.

As the Chairwoman of the Federal Trade Commission ("FTC") has explained, "biologic medicines are among the most important pharmaceuticals available today, providing life-saving therapies for difficult-to-treat diseases such as cancer, diabetes and multiple sclerosis. They are also among the most expensive, with costs often exceeding tens of thousands of dollars per year." FTC, *Follow-On Biologics Workshop*, Tr. 8 (Feb. 4, 2014) (statement of Edith Ramirez).[1] "Introducing

[1] https://www.ftc.gov/system/files/documents/public_events/171301/140204biologicstranscript.pdf.

competition into the biologics market place represents one of the most promising ways to reduce prices and expand access to these critical drugs." *Id.* at 8-9.

As the petition explained (Pet. 27-31), the BPCIA therefore struck a balance between competition and innovation by ensuring biologic drug sponsors a twelve-year period of exclusivity from biosimilar competition, to be extended only in expressly defined circumstances. 42 U.S.C. § 262(k)(7)(A); *id.* § 262(m)(2)(A) (adding six months' exclusivity for successful pediatric studies). As explained by one of Sandoz's several amici, the length of the exclusivity period "was a particularly hard-fought piece" of the BPCIA. Biosimilars Council Br. 6. The Federal Circuit's ruling disrupts that statutory balance: it gives sponsors six more months of "extra-statutory exclusivity." Pet. App. 44a (Chen, J., dissenting). Although Amgen quibbles with calling those additional six months "exclusivity" (Opp. 23-25), it does not deny that the ruling means that no biosimilar can launch until at least six months after FDA approval, necessarily granting every reference product twelve-*and-a-half* years without any competing biosimilar on the market.[2]

Amgen agrees that "the BPCIA is an important new statute, and that its proper interpretation is an

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[2] Amgen points to competition from Granix®, a biologic approved under the more onerous, pre-BPCIA approval process in subsection (a). *See* Opp. 23-25. That says nothing about the balance Congress struck with respect to the BPCIA's subsection (k) biosimilar process.

issue of great importance to innovative biopharmaceutical companies, to those who would propose to make biosimilar versions of those innovators' products, and to the public." Opp. 31. Nevertheless, Amgen tells this Court to wait. Opp. 31-36.

But no good reason exists to defer review. This case presents the *only* foreseeable vehicle to decide whether applicants must await FDA approval before providing notice of commercial marketing. As Amgen acknowledges, "there cannot be a split in the circuit courts here" because "the Federal Circuit's jurisdiction is exclusive in actions arising under the BPCIA." Opp. 32. Future Federal Circuit panels and district courts are bound by this decision. The pending appeal in *Amgen Inc. v. Apotex Inc.* (Opp. 4, 33) does not present the timing issue, and Amgen does not contend otherwise.

In any event, to the extent decisions in pending cases might assist this Court, the Court is likely to have the benefit of at least some of them when it considers the merits here. Moreover, many of the questions being litigated in lower courts would be obviated if this Court were to hold that notice can precede FDA approval.

Contrary to Amgen's suggestion (Opp. 35-36), there is tremendous urgency. Granting certiorari now could prevent delay in market entry for dozens of potential biosimilars in the near term: as of December 2015, seven biosimilar applications were pending at the FDA, and at least thirty-three additional biosimilars were in the last phase of pre-application clinical

trials. IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the U.S.* 24 (2016).[3]

The potential cost savings to patients and payors (including the federal government) from competing biosimilars are enormous. Although Amgen asserts that "Sandoz is pricing ZARXIO® at only a 15% discount" (Opp. 36), a 15% discount on the $92 billion spent on biologics in 2013 (Biosimilars Council Br. 4) would have been a $13.8 billion savings. And the FTC concluded that 10%-30% biosimilar discounts would deliver "substantial consumer savings." FTC, *Emerging Healthcare Issues: Follow-On Biologic Drug Competition* v (June 2009);[4] *accord* FTC Staff Comment in Response to FDA Request for Comments 5, FDA Docket No. FDA-2013-D-1543 (2015).[5]

B. The Federal Circuit's Ruling Regarding The Notice Of Commercial Marketing Provision Is Wrong

This Court's intervention also is needed because the Federal Circuit added an extra-textual requirement to the statute and then added its own federal injunctive remedy to enforce its invented requirement.

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[3] http://www.imshealth.com/en/thought-leadership/ims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020.

[4] https://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report.

[5] https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-submitted-food-drug-administration-response-fdas-request-comments-its-guidance/151028fdabiosimilar.pdf.

As Sandoz explained (Pet. 23-27), subsection (*l*)(8)(A) calls only for the applicant to provide notice to the sponsor "180 days before the date of the first commercial marketing" of its biosimilar. 42 U.S.C. § 262(*l*)(8)(A). Nothing mandates that the notice come after FDA approval. Had Congress intended notice to be provided *after* FDA approval and 180 days *before* commercial marketing, it would have said so directly. Pet. 23.

As the petition also explained (Pet. 31-37), the Federal Circuit went on to devise its own federal remedy: an automatic injunction barring the marketing of an approved biosimilar until 180 days after post-approval notice. That creation of an extra-statutory remedy cannot be reconciled with this Court's decisions or those of other circuits. Pet. 31-32. Congress expressly provided a different remedy: the sponsor's right to bring a declaratory judgment action for patent infringement and a bar on a declaratory judgment suit by the applicant. 42 U.S.C. § 262(*l*)(9)(B).

1. Amgen's arguments about the notice provision can be addressed at the merits stage

Amgen makes a series of arguments about the interpretation of subsection (*l*)(8)(A)—all of which can be addressed at the merits stage and are wrong in any event.

Contrary to Amgen's suggestion (Opp. 16-18), the word "licensed" in the phrase "the biological product licensed under subsection (k)" does not suggest that licensure must precede notice. "[L]icensed" in this

phrase is not "the past tense of a verb" (Opp. 17); it is an adjective describing "product." As the district court correctly explained, "'licensed' refers only to 'biological product'"—which necessarily will be licensed by the time of marketing—"not the appropriate time for notice." Pet. App. 75a. That phrase simply identifies the biological product whose commercial marketing is relevant to measuring the 180-day period. Pet. 24.

Amgen also argues that if subsection (*l*)(8)(A) were referring to a not-yet-approved product, Congress would have used the phrase "the biological product that is the subject of the subsection (k) application" to identify the product whose commercial marketing measures the 180-day period. Opp. 17 (quotation marks omitted). But if Congress had used that phrase to identify the product, that might have suggested notice could be given *only* before approval. Instead, the text of subsection (*l*)(8)(A) does not measure the timing of the notice by the date of FDA approval at all; the timing is measured only by "the date of the first commercial marketing." 42 U.S.C. § 262(*l*)(8)(A).

Noting that the term "subsection (k) applicant" is defined as "a person that submits an application under subsection (k)," *id.* § 262(*l*)(1)(A), Amgen argues that the notice provision's use of that term does not matter because an applicant remains "the subsection (k) applicant" even after approval. Opp. 22. But if Congress meant to mandate that notice be given only after approval, it would not have used "applicant" at all. Instead, it would have referred to the "holder" of an approved application, as it did elsewhere. *See* 42 U.S.C.

§ 262(m)(3). By using "subsection (k) applicant," Congress made clear that notice can be given *before or after* approval because (as Amgen acknowledges) an applicant is a "subsection (k) applicant" both before and after.

Turning to policy arguments, Amgen suggests that the notice should come after approval because of the "possibility of changes in the product or its uses" between application and approval. Opp. 20. But that rationale contradicts a central purpose of the BPCIA: facilitating resolution of patent disputes before approval. This purpose is fulfilled only if notice can be provided before approval. Pre-BPCIA law already provided a way to resolve patent disputes after licensure, or even when licensure was imminent: a declaratory judgment suit for infringement under 35 U.S.C. § 271(a) and/or (g). Pet. 26-27. The BPCIA created "artificial" acts of infringement precisely so litigation could occur *before* any imminent infringement.

Next, trying to make sense of requiring "notice" after the public act of licensure, Amgen asserts that the purpose of notice is "so that the Sponsor will know *when* the Applicant will commence marketing" because "[i]t cannot be presumed that commercial marketing will always follow 180 days after approval." Opp. 22. But even under Amgen's interpretation, the applicant is not required to definitively state when it will market; subsection (*l*)(8)(A) calls simply for notice that marketing will begin *at least* 180 days later.

None of Amgen's other merits arguments on the minutiae of the statute is reason to deny review. First, the separate "interchangeability" provisions of the BPCIA have nothing to do with whether notice can be provided before approval. *Contra* Opp. 18-19. Second, Sandoz's reading would not render "meaningless" the stay provision in subsection (*l*)(9)(A). *Contra* Opp. 19. That provision provides a stay in all situations where there is time between an applicant's disclosure of its biosimilar application and its notice of commercial marketing. In the specific fact pattern posited by Amgen—where an applicant gives notice as soon as it files its application—the applicant simply forgoes the benefits of the stay. But the applicant still provides notice, thus triggering the sponsor's ability to sue on all its patents. Third, Amgen suggests that under Sandoz's reading, the supposed "180-day period" during which the sponsor can "mov[e] for a preliminary injunction" under subsection (*l*)(8)(B) might elapse before identifying the patents on which an injunction could be sought. Opp. 19. Amgen's premise is mistaken. Subsection (*l*)(8)(B) does not limit a sponsor to 180 days to seek an injunction; it allows the sponsor to do so at any time after notice and before marketing. 42 U.S.C. § 262(*l*)(8)(B).

2. *Contrary to Amgen's assertions, the Federal Circuit ruled on the questions presented in Sandoz's petition*

Amgen makes no effort to grapple with decisions from this Court and other courts of appeals rejecting extra-textual private rights of action and remedies,

such as the injunctive remedy under the BPCIA created by the Federal Circuit. *See* Pet. 31-35. Instead, Amgen raises purported vehicle issues, noting that it sued to enforce its reading of the BPCIA only through state law causes of action, without claiming an implied federal cause of action. Opp. 28.

But the Federal Circuit's decision makes clear that its injunction was not based on state law. The Federal Circuit held that Amgen's appeal of the dismissal of its California claim based on Sandoz's notice was "moot" precisely because the court of appeals already had determined to grant Amgen federal injunctive relief based directly on the BPCIA. Pet. App. 27a-28a. As the Federal Circuit explained, it granted an injunction through September 2, 2015 (180 days after Sandoz's post-approval notice) "[i]n light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA." Pet. App. 31a. That this injunction was based on a newly minted federal action directly under the BPCIA is confirmed by the injunction's nationwide scope. A California cause of action could have supported an injunction only as to "conduct occurring within California." *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1360 (Fed. Cir. 2013).

Amgen argues that, rather than fashioning a new remedy, the Federal Circuit granted an injunction pending appeal under Rule 8(a) of the Federal Rules of Appellate Procedure. Opp. 29-31. Although the court granted such an injunction when the case was first appealed (CAFC Dkt. No. 105), Rule 8 was not (and could

not have been) the basis of the injunction created by its ultimate decision. That injunction was not one that lasted "pending" the appeal; to the contrary, the court "extend[ed]" the injunction only to a particular date, September 2, 2015, based on its judgment on the merits. Pet. App. 28a. In fact, the Federal Circuit denied Amgen's request for an injunction pending consideration of en banc review. CAFC Dkt. No. 128.

Contrary to its position in this Court, Amgen has recognized elsewhere that the Federal Circuit's injunction was based directly on the BPCIA, not Rule 8. In urging this Court to defer consideration of the question whether there is a private right of action under the BPCIA, Amgen points to another case it has filed. Opp. 29. Amgen told the district court in that case that the Federal Circuit's decision *in this case* held that a private right of action exists under the BPCIA: "As in *Amgen*, a private cause of action must exist to permit the Court to enforce the statute." Pls.' Answering Br. in Opp. to Def.'s Mot. to Dismiss 9, *Amgen Inc. v. Hospira, Inc.*, No. 1:15-cv-00839-RGA (D. Del. Dec. 3, 2015), ECF No. 17. There, Amgen contended that to conclude otherwise "would be at odds with *Amgen*, where the Federal Circuit entered injunctive relief against Sandoz." *Ibid.*

That Amgen did not itself press for an implied federal right of action here is therefore of no moment for present purposes. The Federal Circuit necessarily decided there was such a right, thus squarely presenting

the issue for this Court's review. *United States v. Williams*, 504 U.S. 36, 41 (1992) (issue reviewable if "not pressed so long as it has been passed upon").[6]

Amgen also argues that because Sandoz provided a second notice after FDA approval, this case does not present the question whether subsection (*l*)(9)(B) "is the exclusive remedy available to a Sponsor where an Applicant fails to give timely notice of commercial marketing." Opp. 27. But that provision covers both when the applicant gives no notice and when it gives notice and launches fewer than 180 days after doing so: in either situation, the applicant has "fail[ed] to complete an action required of the subsection (k) applicant under * * * paragraph (8)(A)." 42 U.S.C. § 262(*l*)(9)(B). And again, Amgen is telling another court something different than it is telling this Court. In a pending Federal Circuit appeal, in which the applicant Apotex has given *no* notice, Amgen contends that the decision in this case governs that fact pattern—"the majority held in *Amgen v. Sandoz*: the [sponsor] is not *required* to bring a declaratory-judgment action" under subsection (*l*)(9)(B)." Amgen Br. 47-48, *Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. Feb. 4, 2016), ECF No. 67; *see id.* at 56.

Finally, contrary to Amgen's suggestion (Opp. 30), Sandoz's second notice did not "commit[] not to do" anything; it was expressly "without prejudice" to Sandoz's

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[6] By contrast, with respect to the issue presented by Amgen's conditional cross-petition, the question of a federal right of action and remedy was neither pressed *nor* passed on. *See* 15-1195 Sandoz Opp. 24-34.

positions in this litigation (CA JA A1774). Sandoz has consistently contested the propriety of *any* injunction to compel compliance with the terms of the notice provision, contending that the BPCIA provides other consequences for not following its terms. *E.g.*, Sandoz CA Br. 46-54; Sandoz CA Reh'g Pet. 10-14.[7] Because the BPCIA expressly provided remedies, the Federal Circuit should not have created its own. *Karahalios v. Nat'l Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989).

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[7] Amgen's oral argument quotation (Opp. 30) omits the end of Sandoz's counsel's sentence—"under their theories"—which made clear she was simply noting the "outside date" an injunction could last under *Amgen's* position. CA Oral Arg. 35:42-35:55, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1499.mp3. Later, Sandoz's counsel emphasized that, except for the confidentiality provision in subsection (*l*)(1)(H), "Congress provided no remedies to compel any step. Instead, it said if they aren't followed, you go immediately to the patent infringement suit." *Id.* at 42:19-42:28.

CONCLUSION

For all these reasons and those in Sandoz's petition, the petition should be granted.

Respectfully submitted,

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MAY 31, 2016

RECORD AND BRIEFS

Supreme Court, U.S.
FILED
DEC - 7 2016
OFFICE OF THE CLERK

Nos. 15-1039 and 15-1195

In the Supreme Court of the United States

SANDOZ INC., PETITIONER

v.

AMGEN INC., ET AL.

AMGEN INC., ET AL.,
CONDITIONAL CROSS-PETITIONERS

v.

SANDOZ INC.

ON PETITION AND CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) establishes an expedited process for licensing "biosimilar" versions of licensed biologic products ("reference products"). 42 U.S.C. 262(k). In conjunction with that process, the BPCIA establishes a series of steps for the resolution of potential patent claims by the sponsor of the reference product and the biosimilar applicant. § 262(*l*). Among other things, Subsection (*l*)(2)(A) of Section 262 provides that the applicant "shall provide to" the sponsor a copy of the biosimilar application and information about the product's manufacturing processes. Subsection (*l*)(8)(A) provides that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

1. The questions presented in the certiorari petition are (a) whether notice of commercial marketing under Subsection (*l*)(8)(A) is legally effective if it is given before Food and Drug Administration (FDA) approval of the biosimilar application, and, if not, (b) whether Subsection (*l*)(8)(A) is a stand-alone requirement that may be enforced by means of an injunction that delays the marketing of the biosimilar until 180 days after FDA approval.

2. The question presented in the conditional cross-petition is whether Subsection (*l*)(2)(A) creates a binding disclosure obligation that a court may enforce by injunction, or whether the sponsor's sole recourse for the applicant's failure to disclose the information is the right, prescribed elsewhere in the BPCIA, to commence an immediate action for patent infringement.

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ON PETITION AND CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

INTEREST OF THE UNITED STATES

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, both the petition and conditional cross-petition for a writ of certiorari should be granted.

STATEMENT

1. This case concerns the statutory processes in Section 351(*l*) of the Public Health Service Act, 42

U.S.C. 262(*l*) (hereinafter Section 262(*l*)), for facilitating the resolution of certain patent disputes that arise in connection with Food and Drug Administration (FDA) licensing of "biological products" (also known as "biologics") under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, Tit. VII, Subtit. A, §§ 7001-7003, 124 Stat. 804-821.[1]

A "biological product" is "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein * * * , or analogous product * * * applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. 262(i)(1). Biologics may be "isolated from a variety of natural sources—human, animal, or microorganism"—and generally are more complex than drugs that FDA approves under 21 U.S.C. 355. Pet. 2 (citation omitted).

a. Section 262 establishes two routes for biologic licensing. 42 U.S.C. 262(a)(1)(A). First, FDA may license a biologic under Section 262(a) if, *inter alia*, the biologic itself has been demonstrated to be "safe, pure, and potent." § 262(a)(2)(C)(i). Second, the BPCIA provides, in Section 262(k), an abbreviated licensing process generally analogous to the process for approving generic drugs under the Hatch-Waxman Amendments, 21 U.S.C. 355(j). Under Section 262(k), FDA may approve an abbreviated biologic license application (aBLA) if, *inter alia*, the biologic at issue is shown to be "biosimilar" to a previously approved biologic (*i.e.*, the "reference product"). 42 U.S.C. 262(k)(3)(A) and (4)(A)(i); see § 262(i)(2) and (4). Developing a biosimi-

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[1] The BPCIA's primary provisions are codified at 35 U.S.C. 271(e)(2)(C), (4)(D), and (6) and 42 U.S.C. 262(i), (k)-(m).

lar generally is substantially more expensive and time-consuming than developing a generic drug. Pet. 2.

An applicant seeking a license for a follow-on biologic may pursue either of the two routes just described. But if it elects to submit an aBLA, the BPCIA prohibits such an aBLA from being submitted earlier than four years after FDA first licensed the reference product and prohibits FDA from making its approval effective earlier than 12 years after that first licensing of the reference product. 42 U.S.C. 262(k)(7)(A) and (B).

b. A reference product may also be protected by various patents, including product or composition patents, manufacturing-process patents, and method-of-use patents. Without the BPCIA's provisions regarding resolution of patent claims, the litigation of patent claims *before* a biosimilar is licensed and marketed would have faced greater difficulties, because parties litigating such claims, including issues of patent invalidity, would have had to overcome ripeness concerns. Cf. 35 U.S.C. 271(a) (patent infringement includes "mak[ing], us[ing], offer[ing] to sell, or sell[ing] any patented invention").

i. The BPCIA facilitates early resolution of patent claims by establishing a so-called "artificial" patent-infringement claim that may be litigated while FDA reviews an aBLA. Cf. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 675-678 (1990) (discussing "artificial" infringement claims in generic-drug context). Under 35 U.S.C. 271(e)(2)(C), the act of submitting an "application seeking approval of a biological product" is an "act of infringement" if the "purpose of such submission is to obtain approval * * * to engage in the commercial manufacture, use, or sale of a * * * bio-

logical product claimed in a patent or the use of which is claimed in a patent" before the patent expires. 35 U.S.C. 271(e)(2)(C).

ii. Section 262(*l*), in turn, establishes a four-phase process for resolving patent disputes in two rounds of patent litigation between the aBLA applicant (applicant) and the reference-product sponsor (sponsor). See 42 U.S.C. 262(*l*)(2)-(8). This brief refers to those phases as the (1) Information Phase, § 262(*l*)(2); (2) Comprehensive List Phase, § 262(*l*)(3); (3) Round 1 Litigation Phase, § 262(*l*)(4)-(6); and (4) Round 2 Litigation Phase, § 262(*l*)(8) and (9)(A). The BPCIA further provides detailed consequences for failing to follow Section 262(*l*)'s patent-dispute-resolution process. See 35 U.S.C. 271(e)(2)(C) and (6); 42 U.S.C. 262(*l*)(9)(B) and (C). Those consequences, as explained below, can accelerate the timing, and modify the scope, of the ensuing patent litigation.

First, in the Information Phase, the applicant "shall provide to the * * * sponsor," within 20 days of FDA's acceptance of its aBLA for review, both a copy of the aBLA and manufacturing-process information. 42 U.S.C. 262(*l*)(2)(A). The sponsor's "confidential access" to that "information required to be produced pursuant to [Subsection (*l*)](2)" is for the "sole and exclusive purpose" of allowing the sponsor to determine "whether a claim of patent infringement could reasonably be asserted" against the applicant. § 262(*l*)(1)(B)(i) and (D); see § 262(*l*)(1)(H) (authorizing "immediate injunctive relief" for improper disclosure).

If the applicant, however, "fails to provide the application and information required under [S]ection [262](*l*)(2)(A)," the applicant's submission of its aBLA

is deemed an artificial act of infringement. 35 U.S.C. 271(e)(2)(C)(ii). The "sponsor, but not the * * * applicant," may then bring a declaratory-judgment action based on "any patent that claims the biological product or a use of the biological product." 42 U.S.C. 262(*l*)(9)(C). The question presented by respondents' conditional cross-petition (at ii, 31-33) concerns whether, in addition to those express statutory consequences, a court may also compel the applicant to provide the Subsection (*l*)(2)(A) information to the sponsor.

Second, in the Comprehensive List Phase, the sponsor and applicant produce a list of the patents on which infringement claims could reasonably be asserted. 42 U.S.C. 262(*l*)(3). Within 60 days of receiving the applicant's aBLA and manufacturing information, the sponsor "shall provide" to the applicant a list of such patents and identify which patents it would be prepared to license. § 262(*l*)(3)(A). If the sponsor fails timely to include "a patent that should have been included in the list," the sponsor cannot later assert any claim for "infringement of the patent with respect to the [applicant's biosimilar]." 35 U.S.C. 271(e)(6)(C).

Within 60 days after receipt of the sponsor's list, the applicant "may provide" the sponsor with its own list of patents on which it believes a claim of "infringement could reasonably be asserted"; "shall provide" a response to each patent on the sponsor's list explaining why commercially marketing the biosimilar will not violate the sponsor's patent rights; and "shall provide" a response to the sponsor's licensing offer. 42 U.S.C. 262(*l*)(3)(B). Within 60 days after receipt of the applicant's list, the sponsor then "shall provide" the applicant a detailed statement why the patents on the sponsor's list would be infringed and a response

concerning the validity and enforceability of patents on the applicant's list. § 262(*l*)(3)(C).

The applicant's submission of its aBLA is an artificial act of infringement "with respect to a patent that is identified in the list of patents described in section [262](*l*)(3)," *i.e.*, in the Comprehensive List. 35 U.S.C. 271(e)(2)(C)(i). As discussed below, however, other BPCIA provisions control the timing and scope of any resulting patent-infringement claims, which can proceed in two potentially overlapping rounds of litigation.

Third, in the Round 1 Litigation Phase, the applicant and sponsor identify the patents for prompt (Round 1) infringement litigation. 42 U.S.C. 262(*l*)(4)-(6). The applicant and sponsor negotiate which patents from the Comprehensive List should be promptly litigated. If within 15 days they reach agreement on such a "list of * * * patents," the "sponsor shall bring an action for patent infringement with respect to each such patent" within 30 days. § 262(*l*)(4) and (6)(A).

If they do not reach agreement within 15 days, the applicant "shall notify" the sponsor of "the number of patents" that the applicant will designate for its Round 1 list; then within five days, the applicant and sponsor "shall simultaneously" exchange their Round 1 lists. 42 U.S.C. 262(*l*)(5)(A) and (B)(i). The "number of patents listed" by the sponsor for Round 1 litigation may not exceed the number listed by the applicant, although if the applicant lists no patents the sponsor may list one. § 262(*l*)(5)(B)(ii). The sponsor then "shall bring an action for patent infringement" for each patent on the Round 1 lists within 30 days. § 262(*l*)(6)(B).

If the applicant and sponsor successfully complete the actions required of them in the Information, Comprehensive List, and Round 1 Litigation Phases, the sponsor's Round 1 patent action will be filed roughly 250 days or less after FDA accepts the applicant's aBLA for review. See 42 U.S.C. 262(*l*)(2)-(6). But if the sponsor fails to file the Round 1 litigation within the requisite 30-day period, or if its action for infringement of a patent on a Round 1 list is dismissed without prejudice or not prosecuted in good faith, the sponsor's "sole and exclusive" remedy for infringement of such a Round 1 patent is limited to a "reasonable royalty." 35 U.S.C. 271(e)(6)(A) and (B). That effectively grants an applicant that loses a subsequent infringement action a compulsory license for any such Round 1 patent.

Fourth, the Round 2 Litigation Phase covers the non-Round-1 patents, *i.e.*, the remaining patents on the Comprehensive List not included on a Round 1 list. Cf. 42 U.S.C. 262(*l*)(8)(B)(i) and (ii) (remaining patents). The BPCIA normally postpones litigation on the Round 2 patents. Specifically, if the applicant timely provided the sponsor with the information required in Subsection (*l*)(2)'s Information Phase, neither the sponsor nor the applicant may bring a declaratory-judgment action based on a Round 2 patent before the applicant provides advance notice of the first commercial marketing of its biosimilar. § 262(*l*)(9)(A).

Section 262(*l*)(8)(A)—the central provision at issue in the certiorari petition—governs the timing of that notice. It provides that the "applicant shall provide notice" to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [Section 262](k)." 42

U.S.C. 262(*l*)(8)(A). The questions presented in the certiorari petition (at ii) are whether that notice may be given before FDA approval of the biosimilar and, if not, whether a court may enjoin the applicant's marketing of its biosimilar for 180 days after FDA approval.

When such notice is given, the BPCIA's postponement of litigation on the Round 2 patents ends, 42 U.S.C. 262(*l*)(9)(A), allowing the sponsor to bring suit on those patents. In addition, "[a]fter receiving the notice * * * and before * * * the first commercial marketing" of the biosimilar, the "sponsor may seek a preliminary injunction" to enjoin the commercial manufacture or sale of the biosimilar "until the court decides the issue of patent validity, enforcement, and infringement with respect to any [Round 2] patent." § 262(*l*)(8)(B).

Alternatively, even before any notice is given under Section 262(*l*)(8)(A), the BPCIA's postponement of patent litigation terminates if the "applicant fails to complete an action required of [it]" under certain provisions of Section 262(*l*). 42 U.S.C. 262(*l*)(9)(B). Specifically, the "sponsor, but not the * * * applicant," may bring a declaratory-judgment action on any patent on the sponsor's Comprehensive List (including any relevant Round 2 patent) if the applicant "fails" to provide the sponsor with its timely explanation why marketing the biosimilar would not violate the sponsor's rights under patents on the sponsor's list (§ 262(*l*)(3)(B)(ii)); to provide the sponsor timely notice of the applicant's number of Round 1 patents or its Round 1 list (§ 262(*l*)(5)); to provide the Secretary of Health and Human Services with a timely copy of a complaint in the Round 1 litigation

(§ 262(*l*)(6)(C)(i)); or to provide the sponsor the 180-day advance notice of the biosimilar's first commercial marketing (§ 262(*l*)(8)(A)). See § 262(*l*)(9)(B).

2. Respondents have marketed filgrastim under the brand name Neupogen since 1991. Pet. App. 8a. In May 2014, petitioner filed an aBLA seeking FDA approval of a biosimilar filgrastim product (with the trade name Zarxio) that listed Neupogen as its reference product. *Id.* at 8a-9a. On July 7, 2014, FDA notified petitioner that it had accepted the aBLA for review. *Id.* at 8a.

On July 8, 2014, petitioner notified respondents of the filing of petitioner's aBLA and stated that petitioner intended to launch its biosimilar immediately upon FDA approval, which it expected in "Q1/2 of 2015." Pet. App. 8a. Petitioner, however, elected not to provide respondents with a copy of its aBLA or manufacturing-process information under Section 262(*l*)(2)(A). *Ibid.* Petitioner informed respondents that respondents were therefore entitled to sue petitioner for patent infringement. *Ibid.*

3. In October 2014, respondents filed a district court action against petitioner, asserting a patent-infringement claim based on a patent claiming a method of using filgrastim, and an unfair competition law (UCL) and a conversion claim under California law. Pet. App. 9a. Respondents' UCL claim was based on two alleged violations of the BPCIA: petitioner's failure to disclose information required by Section 262(*l*)(2)(A), and its allegedly ineffective advance notice of commercial marketing under Section 262(*l*)(8)(A). *Ibid.* Petitioner counterclaimed for a declaratory judgment on both BPCIA questions and on its contentions that respondents' patent was invalid

and not infringed. *Ibid.* Respondents sought a preliminary injunction based on its state-law claims to prevent petitioner from marketing its biosimilar. *Id.* at 9a-10a, 57a-58a. Respondents subsequently obtained petitioner's aBLA in discovery. *Id.* at 10a.

Later, on March 6, 2015, FDA approved petitioner's aBLA for all approved uses of Neupogen. Pet. App. 8a-9a. That same day, petitioner gave respondents a second, "further notice of commercial marketing." *Ibid.*

Shortly thereafter, the district court denied injunctive relief and granted petitioner partial judgment on the pleadings. Pet. App. 56a-84a. The court concluded that petitioner permissibly declined to provide its aBLA and manufacturing-process information under Section 262(*l*)(2)(A), *id.* at 68a-73a, and permissibly gave notice under Section 262(*l*)(8)(A) before FDA approved its aBLA, *id.* at 73a-76a. The court rejected respondents' UCL claim on those federal-law grounds, *id.* at 77a-78a, and separately rejected respondents' state-law conversion claim, *id.* at 78a-79a. The court subsequently entered a Rule 54(b) partial final judgment on respondents' state-law claims and petitioner's BPCIA counterclaims. *Id.* at 11a.

4. The Federal Circuit granted an injunction pending appeal that prohibited petitioner from marketing Zarxio, Pet. App. 31a, and subsequently affirmed in part, vacated in part, and remanded. *Id.* at 1a-55a.

a. The court of appeals first concluded that petitioner could elect not to disclose its aBLA and manufacturing information under Section 262(*l*)(2)(A), subject only to the patent-litigation consequences specified in the BPCIA. Pet. App. 12a-18a. Although Section 262(*l*)(2)(A) states that the applicant "shall" pro-

vide that information, the court concluded that that word and related statutory language must be understood in their broader statutory context. *Id.* at 14a-15a. Other BPCIA provisions in 35 U.S.C. 271(e)(2)(C)(ii) and 42 U.S.C. 262(*l*)(9)(C), the court explained, not only "explicitly contemplate" that the applicant might not provide that information, but also "specifically set[] forth the consequences for such failure: the [sponsor] may bring an infringement action," and the applicant is prohibited from bringing its own "action on patents that claim the biological product or its use." Pet. App. 15a-17a. Given that the BPCIA does not "specify any non-patent-based remedies" for failing to comply with Section 262(*l*)(2)(A), the court concluded that the sponsor's only recourse is to pursue a patent action, in which the sponsor can then "access the required information through discovery." *Id.* at 17a-18a. Judge Newman dissented from that holding. *Id.* at 32a-42a.

b. The court of appeals concluded, however, that an aBLA applicant must give notice of the date of first commercial marketing under Section 262(*l*)(8)(A) *after* FDA approves the applicant's aBLA. Pet. App. 18a-26a. The court reasoned that the requirement to give notice 180 days before the first commercial marketing of the applicant's "biological product licensed under [Section 262](k)," 42 U.S.C. 262(*l*)(8)(A), contemplates that the biosimilar must be "licensed" before the notice is given. Pet. App. 20a-21a. The court believed that the "purpose of [Section 262](*l*)(8)(A) is clear": "to allow the [sponsor] a period of time to assess and act upon its patent rights." *Id.* at 25a-26a. The court then "extended" its injunction forbidding the marketing of Zarxio until September 2, 2015, *i.e.*, 180 days

after petitioner gave its second notice to respondents. *Id.* at 27a-28a, 31a.

Judge Chen dissented from that holding, concluding that petitioner had no independent obligation to provide notice under Section 262(*l*)(8)(A). Pet. App. 42a-55a. That provision, Judge Chen explained, is not a "standalone provision" but rather is a part of "the integrated litigation management process contemplated in (*l*)(2)-(*l*)(7)," and when, as here, the "applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Id.* at 43a.

c. The court of appeals affirmed the dismissal of respondents' UCL claim based on an alleged violation of Section 262(*l*)(2)(A), Pet. App. 26a-27a, and deemed respondents' UCL claim based on petitioner's violation of Section 262(*l*)(8)(A) to be moot in light of the court's extension of its injunction, *id.* at 27a-28a. The court affirmed the dismissal of respondents' conversion claim. *Id.* at 28a-29a.

DISCUSSION

Petitioner challenges (Pet. 22-36) the Federal Circuit's conclusions that an applicant may provide the 180-day advance notice of first commercial marketing of its biosimilar under Section 262(*l*)(8)(A) only *after* FDA has licensed that biosimilar, and that a court may enforce Section 262(*l*)(8)(A) by enjoining the applicant from such marketing until 180 days after the applicant provides that notice. Respondents, in turn, challenge (Cross-Pet. 25-40) the court's determination that where an applicant fails at the outset to provide the sponsor with its aBLA and manufacturing-process information under Section 262(*l*)(2)(A), the sponsor's only recourse under the BPCIA is to bring an immediate patent suit. The court of appeals erred in inter-

preting Subsection (*l*)(8)(A), but it correctly construed Subsection (*l*)(2)(A). The proper interpretation of those provisions has a significant impact on the operation of the BPCIA and the ability of aBLA applicants promptly to bring their biosimilars to the public. And because the provisions are integrally related, the Court should consider all of the questions presented together. Both the certiorari petition and conditional cross-petition therefore should be granted.

A. Providing Notice Of Commercial Marketing Before FDA Approval Is Consistent With Section 262(*l*)(8)(A), And Injunctive Relief Is Not Available For A Failure To Furnish Notice Under That Provision

Section 262(*l*)(8)(A) allows the applicant to give the requisite 180-day advance notice of the first commercial marketing of its biosimilar before FDA has approved the applicant's biosimilar application. But in any event, no federal cause of action exists under which a sponsor could obtain injunctive relief if the applicant fails to give notice as specified in Section 262(*l*)(8)(A).

1. The text and purpose of Section 262(*l*)(8)(A)'s notice provision and the BPCIA's broader statutory context demonstrate that the provision permits an applicant to give advance notice of the first commercial marketing of its biosimilar before FDA has licensed the biosimilar.

a. Section 262(*l*)(8)(A)'s text directly addresses the requisite timing. Notice must be given "not later than 180 days *before* the date of the first commercial marketing." 42 U.S.C. 262(*l*)(8)(A) (emphasis added). That restriction places the only limit on the appropriate timing. Nothing in Section 262(*l*)(8)(A) additionally restricts how soon the applicant may provide notice

after the applicant submits its aBLA to FDA. That straightforward conclusion from the absence of such a further limit is reinforced by the very next sentence of Subsection (*l*)(8), where Congress expressly provided that the sponsor may seek a preliminary injunction to enjoin such marketing "[*a*]*fter* receiving the notice * * * *and before* [the] date of the first commercial marketing," § 262(*l*)(8)(B) (emphasis added).

The Federal Circuit inferred a temporal restriction from the phrase "the date of the first commercial marketing of the biological product licensed under [Section 262](k)," 42 U.S.C. 262(*l*)(8)(A), because, it concluded, the word "licensed" indicates that the notice "must be given only after the product is licensed." Pet. App. 20a-21a. But "licensed" there is most naturally read as describing the biological product at "the *date* of [its] first commercial marketing," § 262(*l*)(8)(A) (emphasis added). And Section 262(*l*)(8)(A) simply requires notice be given "not later than 180 days before th[at] date," *ibid.*, a time at which the product may not yet be licensed. That textual focus on the date upon which actual marketing will occur distinguishes Section 262(*l*)(8)(A) from other provisions, cited by the court of appeals (Pet. App. 20a), that require an entity to communicate its opinion about the possible patent-law implications of a future commercial marketing of the "product that is the subject of the subsection (k) application" (aBLA). See § 262(*l*)(3)(B)(ii)(I) and (C).

Moreover, under the Federal Circuit's reading, the owner of a biosimilar with an effective license could be forced to wait 180 days after FDA has authorized it to commence marketing, even if the sponsor had no arguably valid infringement claim to warrant such delay. The timing of biosimilars' entry onto the market was

a significant issue addressed by the BPCIA, which prohibits FDA from making its approval of an aBLA effective before 12 years after the reference product's first licensure. See 42 U.S.C. 262(k)(7)(A); see also § 262(k)(6), (m)(2)(A), and (3)(A) (expressly granting exclusivity periods). Given the expressly granted exclusivity periods, it is particularly unlikely that Congress would have further delayed biosimilars' marketing in such an indirect manner.

b. The Federal Circuit found its reading preferable because, by requiring that the notice (which triggers Round 2 patent litigation under Section 262(*l*)(9)(A)) be given "*after* FDA licensure," it ensured that any Round 2 litigation would reflect a "fully crystallized controversy." Pet. App. 21a (emphasis added). That rationale runs against Congress's policy judgments in the BPCIA. Congress specifically made the "submi[s-sion]" of the applicant's aBLA ("application") an "act of infringement," 35 U.S.C. 271(e)(2) and (2)(C), to facilitate patent litigation soon after the aBLA's submission, which necessarily occurs before FDA could grant a license. Indeed, a central "part of the [BPCIA's] design" is to afford the applicant significant "control" over "the scope of the [Round 1] litigation," *Amgen Inc.* v. *Apotex Inc.*, 827 F.3d 1052, 1062 & n.3 (Fed. Cir. 2016), petition for cert. pending, No. 16-332 (filed Sept. 9, 2016), by allowing it, for instance, to restrict that litigation to just one patent or, conversely, to expand it to include all relevant patents. See 42 U.S.C. 262(*l*)(5)(B)(i)(I), (ii)(II), and (6)(B); p. 6, *supra*. The BPCIA thus necessarily contemplates that all relevant patents can be placed in Round 1 litigation, litigation that—when the parties follow the schedule in Section 262(*l*)—will commence no later

than roughly 250 days after FDA accepts the aBLA for review. See p. 7, *supra*. The aBLA, morever, may be submitted a full eight years before FDA could grant an effective license. § 262(k)(7)(A) and (B). Accordingly, Congress itself chose to permit patent litigation on *all* relevant patents to commence more than seven years *before* such licensing.

The statutory consequences of failing to take the steps specified in Section 262(*l*)'s patent-dispute process further reflect the purpose of facilitating early litigation of patent claims. If the applicant fails at the outset to provide the sponsor with its aBLA and manufacturing-process information under Subsection (*l*)(2), the applicant loses its right to control the pace and scope of the patent litigation because the sponsor may immediately bring suit on the relevant patents. See 35 U.S.C. 271(e)(2)(C)(ii); 42 U.S.C. 262(*l*)(9)(C); pp. 4-5, *supra*. But if the applicant timely provides that information, the sponsor must then timely identify its Complete List of patents, 42 U.S.C. 262(*l*)(3)(A), lest it forever forfeit its right to assert any claim of infringement based on its patents against the applicant's biosimilar, 35 U.S.C. 271(e)(6)(C). And once the sponsor has identified its Complete List of patents, if the applicant fails to take further actions specified by Section 262(*l*), the BPCIA similarly deprives the applicant of its control over the patent litigation and accelerates its potential pace by authorizing the sponsor to bring suit immediately on all patents on its Complete List. 42 U.S.C. 262(*l*)(9)(B); see pp. 8-9, *supra*.

The Federal Circuit relied on the purported absence of any provision specifically imposing "consequence[s] for[] noncompliance with [Subsection]

(*l*)(8)(A)" that would apply to contexts in which, like here, the applicant has also failed to provide the sponsor information at the outset under Subsection (*l*)(2)(A). Pet. App. 24a-25a. The court correctly noted that the consequence provided in Subsection (*l*)(9)(B) if an applicant does not complete a subsequent action in the multi-step process—*i.e.*, allowing the sponsor immediately to bring suit on all patents on its Complete List—applies only if the applicant initially provided the information required by Subsection (*l*)(2)(A). *Ibid.* But the court failed to recognize that specifically identifying such a consequence for noncompliance with Subsection (*l*)(8)(A) is entirely unnecessary if the applicant failed at the outset to furnish the Subsection (*l*)(2)(A) information. In those circumstances, the BPCIA *already* specifies that the sponsor may bring suit on any relevant patent following such a failure. 35 U.S.C. 271(e)(2)(C)(ii); 42 U.S.C. 262(*l*)(9)(C).

Nor was the Federal Circuit correct that Subsection (*l*)(8)(A)'s notice requirement imposes a "standalone" notice provision in service of a broad purpose of "allow[ing] the [sponsor] a period of time to assess and act upon its patent rights" generally. Pet. App. 25a-26a. The notice serves a more narrowly focused purpose: it triggers a statutory period, ending on the date of the first commercial marketing, during which the sponsor may seek a preliminary injunction to prevent the applicant from engaging in the commercial manufacture or sale of the biosimilar until the court resolves *particular* patent claims. 42 U.S.C. 262(*l*)(8)(B). The patent claims that Subsection (*l*)(8) identifies for resolution are expressly limited to claims involving *Round 2* patents. § 262(*l*)(8)(B)(i) and (ii); cf. § 262(*l*)(9)(A) (commercial-marketing notice lifts

BPCIA's general postponement of litigation of Round 2 patents). Congress concluded that a sponsor should be given a fair chance to litigate the Round 2 patents prior to actual marketing, since the applicant controls the scope of the earlier Round 1 litigation. Subsection (*l*)(8)(A)'s notice requirement therefore is properly viewed as affording the sponsor an adequate opportunity to commence litigation on the Round 2 patents that it previously was prevented from bringing while the applicant was following the process for controlling patent litigation.

But where, as here, the applicant's failure to complete actions required of it by Section 262(*l*) allows the sponsor immediately to institute patent litigation, thereby divesting the applicant of its ability to control the pace and scope of the patent litigation, see 35 U.S.C. 271(e)(2)(C)(ii); 42 U.S.C. 262(*l*)(9)(B) and (C), the special provisions for litigation of Round 2 patents in Subsection (*l*)(8)(B) and (9)(A) lose their significance. Cf. Pet. App. 43a, 48a-49a (Chen, J., dissenting). Even if notice might still be required in those circumstances, as long as the applicant gives notice *at least* 180 days before commercial marketing, as petitioner did here, the sponsor can initiate whatever infringement litigation it wants well before that commercial marketing, and it can do so even if the notice is given at the beginning stages of the regulatory process rather than at the end.

2. The Federal Circuit imposed an injunction to enforce its reading of Section 262(*l*)(8)(A)'s notice requirement. Pet. App. 31a. Although respondents state (Br. in Opp. 29-30) that the court had authority under Rule 8(a) to extend its "injunction pending appeal," that rationale makes little sense because the

court had *resolved* that appeal. The Federal Circuit thus reads its decision here as holding more generally that "an injunction [i]s proper to enforce" Section 262(*l*)(8)(A). *Apotex*, 827 F.3d at 1054, 1060-1061; see *id.* at 1063-1065. That holding is incorrect.

A "private right[] of action to enforce federal law must be created by Congress." *Alexander* v. *Sandoval*, 532 U.S. 275, 286 (2001). "[C]ourts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-287. "[A]n implied cause of action" is recognized "only if the underlying statute can be interpreted to disclose [Congress's] intent to create one." *Stoneridge Inv. Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008). And recognizing a cause of action based on inferred, rather than express, intent is a decidedly "rare step." *Paroline* v. *United States*, 134 S. Ct. 1710, 1725 (2014).

Nothing in the BPCIA creates a cause of action to enforce Section 262(*l*)(8)(A)'s notice provision. The BPCIA's carefully calibrated set of consequences for failing to take actions required under Section 262(*l*)'s patent-dispute process simply modifies the pace and scope of patent-infringement litigation. See pp. 4-5, 7-9, *supra*. The Patent Act's private cause of action for infringement (35 U.S.C. 281), in turn, does not provide for enforcement of Section 262(*l*)(8)(A), because failing to provide notice under Section 262(*l*)(8)(A) does not constitute infringement. See 35 U.S.C. 271. By contrast, Congress did specify the availability of "injunctive relief" for a violation of the confidentiality rules in Section 262(*l*)(1), see 42 U.S.C. 262(*l*)(1)(H), an occurrence that does not halt the ongoing patent-dispute-resolution process. That "carefully crafted and

detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly," *Great-West Life & Annuity Ins. Co.* v. *Knudson*, 534 U.S. 204, 209 (2002) (citation and internal quotation marks omitted), and provides no basis for inferring a private right of action for injunctive or other relief to enforce Section 262(*l*)(8)(A). The sponsor's proper course if notice is not given under Section 262(*l*)(8)(A) is therefore the course contemplated by the BPCIA: an immediate patent-infringement action. See 35 U.S.C. 271(e)(2)(C); 42 U.S.C. 262(*l*)(9)(B).

B. The Sponsor's Recourse If An Applicant Fails To Provide Information Under Section 262(*l*)(2)(A) Is Commencement Of A Patent-Infringement Action

Section 262(*l*)(2)(A) provides that the applicant "shall provide" to the sponsor, within 20 days of FDA's acceptance of its aBLA for review, a copy of the aBLA and manufacturing-process information. 42 U.S.C. 262(*l*)(2)(A). The BPCIA, however, further states that if the applicant "fails to provide the application and information required under [S]ection [262](*l*)(2)(A)," the applicant's submission of its aBLA is deemed an artificial act of infringement, 35 U.S.C. 271(e)(2)(C)(ii), on which the sponsor may bring suit, 35 U.S.C. 281. If the applicant "fails to provide" that information, the "sponsor, but not the * * * applicant," may bring a declaratory-judgment action based on "any patent that claims the biological product or a use of the biological product." 42 U.S.C. 262(*l*)(9)(C). The Federal Circuit held that those BPCIA consequences are exclusive and that, when a sponsor brings its patent action, it may obtain information from the

applicant in discovery. Pet. App. 12a-18a. That holding is correct.

Respondents' conditional cross-petition argues (at 25-32) that the Federal Circuit erred in concluding that Section 262(*l*)(2)(A)'s use of "shall" "does not mean 'must.'" Pet. App. 15a. The government agrees that the Federal Circuit misconceived the relevant inquiry in that respect. But Section 262(*l*)(2)(A) may properly be understood as imposing a mandatory condition for invoking Subsection (*l*)'s patent-dispute framework without concluding that an injunction is available to compel compliance with that condition.

Even if the term "shall" is understood as mandatory, the only consequences for failing to satisfy that condition are those expressly set forth by Congress in the BPCIA. That conclusion flows logically from essentially the same reasons discussed above in connection with Section 262(*l*)(8)(A). See pp. 18-20, *supra*. And as petitioner explains, a sponsor can, after conducting a diligent investigation, file an infringement suit as contemplated by the BPCIA based on any patent it reasonably believes has been infringed, and it may seek additional information regarding that patent claim through discovery. See Cross-Br. in Opp. 21-22.

C. The Petition and Conditional Cross-Petition Present Important Questions Warranting Review

1. The questions presented in the petition and conditional cross-petition address the BPCIA's patent-dispute process that applies to every biosimilar for which FDA approval of an aBLA is sought. Those questions thus are now recurring in other actions pending in various district courts. See, *e.g.*, Pet. 41; Br. in Opp. 33-34. The Federal Circuit exercises ex-

clusive jurisdiction over appeals in any civil action arising under any Act of Congress "relating to patents," 28 U.S.C. 1295(a)(1), and petitioner and respondents agree that no circuit split could arise in this BPCIA context. Br. in Opp. 32; Reply Br. 4.

The questions presented are also sufficiently important to merit the Court's review. "[B]iologic medicines are among the most important pharmaceuticals available today" and "are also among the most expensive, with costs often exceeding tens of thousands of dollars per year."[2] In 2013, biologics accounted for approximately $80 billion in spending in the United States, constituting approximately 25% of all pharmaceutical expenditures. FTC, *Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition*, 78 Fed. Reg. 68,841 (Nov. 15, 2013). The BPCIA represents a carefully calibrated legislative effort to promote innovation and competition in this important field, and the questions presented address core questions governing how the BPCIA operates.

2. This case is an appropriate vehicle through which the Court may resolve those questions, notwithstanding the expiration of the Federal Circuit's injunction in September 2015. Although petitioner is no longer enjoined from marketing Zarxio for allegedly violating Section 262(*l*)(8)(A), see Pet. App. 27a-28a, 31a, petitioner explains (Pet. 36-37) that this case is not moot because the dispute is capable of repetition, yet evading review. Respondents do not appear to

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[2] FTC, *Follow-On Biologics Workshop*, Tr. 8 (Feb. 4, 2014), http://www.ftc.gov/system/files/documents/public_events/171301/140204biologicstranscript.pdf (statement of FTC Chairwoman Edith Ramirez).

dispute that conclusion,[3] and the government concludes that a live controversy continues to exist.

Litigation over Section 262(*l*)(8)(A)'s 180-day advance notice requirement is by its nature "too short to be fully litigated prior to cessation or expiration." *Davis* v. *FEC*, 554 U.S. 724, 735 (2008) (citation omitted). In addition, a "reasonable expectation [exists] that the same complaining party will be subject to the same action again." *Ibid.* (citation omitted). Petitioner is a repeat player in the biosimilar market, Pet. 36-37 & n.10; respondents are industry leaders in "develop[ing] and manufactur[ing] biologic medications";[4] and Section 262(*l*)'s provisions apply to every biosimilar for which FDA approval of an aBLA is sought. Already, in at least one other pending patent action, respondents appear to have alleged an impending Section 262(*l*)(8) violation in connection with petitioner's marketing of another biosimilar. See Compl. at ¶¶ 90, 107, 126, 144, 162, *Immunex Corp.* v. *Sandoz, Inc.*, No. 2:16-cv-1118 (D.N.J.) (filed Feb. 26, 2016). Moreover, the Federal Circuit's exclusive jurisdiction over appeals from actions arising under any Act of Congress "relating to patents," 28 U.S.C. 1295(a)(1), means that the precedential decision in this case will govern the parties' future actions. Cf. *Camreta* v. *Greene*, 563 U.S. 692, 702-703, 709 n.7 (2011) (recognizing ongoing injury from adverse binding precedent governing future actions of litigant who otherwise

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[3] Respondents merely contend that the case is moot because petitioner's second notice was effective under the Federal Circuit's reasoning. Br. in Opp. 26, 28-29. This case, however, concerns whether petitioner's first notice was consistent with the BPCIA.

[4] Amgen, Inc., *Innovation in all we do*, http://www.amgenbiotech.com/manufacturing-innovation.html.

prevailed). Under these circumstances, the case is not moot.

3. Petitioner contends (Cross-Br. in Opp. 24-34) that the Court should not grant the conditional cross-petition because the Section 262(*l*)(2)(A) question the cross-petition presents was resolved in the context of a state-law cause of action. That contention is unpersuasive. The Federal Circuit dismissed respondents' state-law UCL claim "based on [its] interpretation" of the BPCIA, including its view that the BPCIA provides its own exclusive remedies that render UCL relief unavailable. Pet. App. 26a-27a, 29a; see Cross-Reply Br. 10. And the Federal Circuit separately directed the district court to "enter judgment on [petitioner's] counterclaim[]," which sought a declaratory judgment on the proper interpretation of Section 262(*l*)(2)(A). Pet. App. 10a, 31a.

Furthermore, the petition and conditional-cross petition raise interrelated questions concerning the proper operation of Section 262(*l*)'s patent-dispute-resolution process. Given the interlocking nature of the relevant provisions in Section 262(*l*)(2)-(8), granting the conditional cross-petition would ensure that the parties would be able to raise the full set of arguments in support of their positions.

CONCLUSION

The petition and conditional cross-petition for a writ of certiorari should be granted.

Respectfully submitted.

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DECEMBER 2016

RECORD AND BRIEFS

Supreme Court, U.S.
FILED
MAR 21 2016
OFFICE OF THE CLERK

No. 15-1039

IN THE

Supreme Court of the United States

SANDOZ, INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF THE BIOSIMILARS COUNCIL AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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March 21, 2016

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae the Biosimilars Council, a division of the Generic Pharmaceutical Association, files this brief to urge this Court to grant the petition for a writ of certiorari filed by Sandoz, Inc.

The Biosimilars Council's members include companies and stakeholder organizations working to develop biosimilar products for the United States pharmaceutical market. Biosimilars are highly similar or interchangeable versions of Food and Drug Administration ("FDA")-licensed branded biologic medicines. A branded biologic in this context is known as a "reference product" and its licenseholder as the "Reference Product Sponsor" or "RPS." Congress established an expedited FDA approval pathway for biosimilars in 2010 in the Biologics Price Competition and Innovation Act ("BPCIA"), as part of the Affordable Care Act.[2]

This case raises critical issues concerning the proper interpretation of the BPCIA's procedures for

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[1] *Amicus* gave notice of its intention to file this brief on March 4, 2016, and all parties have consented to the brief's filing. No counsel for a party authored this brief, in whole or in part; no counsel for a party made a monetary contribution intended to fund the preparation of submission of this brief; and no one other than *amicus*, its members, or its counsel made such a monetary contribution. Funding for the Biosimilars Council includes regular contributions from its members, including Petitioner.

[2] Reference products are licensed under section 351(a) of the Public Health Services Act ("PHSA"), 42 U.S.C. § 262(a). The expedited biosimilars pathway was added by the BPCIA to the PHSA as section 351(k), 42 U.S.C. § 262(k).

the resolution of patent disputes between a biosimilar applicant and an RPS – specifically, whether Congress intended the "notice of commercial marketing" provisions that are part of these procedures to (1) delay commercial marketing of biosimilars for an additional six months beyond the statute's express 12-year exclusivity period for reference products or (2) confer on an RPS a private right of action to compel notice through an automatic injunction. The Federal Circuit answered these questions "yes," but the correct answers are "no."

Amicus and its members have a strong, industry-wide interest in ensuring that the BPCIA, including the notice provisions, are interpreted consistent with Congress' overriding goal of expediting patients' access to affordable versions of badly needed medicines. The Federal Circuit's erroneous decision, if left uncorrected, would undermine these goals by (1) denying patients access to biosimilars for six months longer than Congress intended and (2) enabling an RPS to effect this delay through an automatic injunction, outside the remedial framework Congress established as part of the BPCIA's patent dispute resolution process.

The Federal Circuit's decision will apply to other biosimilars, not just the Sandoz product at issue in this case, shaping the overall biosimilars landscape just as the BPCIA and the biosimilars industry are coming of age. One district court has already relied on the Federal Circuit's decision to enjoin the marketing

of another biosimilar,[3] similar injunctions have been sought in two other cases,[4] and the notice issue will inevitably resurface in cases involving new biosimilar applications filed with FDA. The industry-wide and nation-wide impact of the Federal Circuit's error, and therefore *amicus*' interest in this Court's plenary review of that decision, is apparent.

STATEMENT

A. The Promise of Biosimilars

Biologics are large-molecule medicines derived from living organisms. They are among the most expensive drug products in the United States and account for an increasing share of U.S. prescription drug costs. Federal Trade Comm'n, Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposal on Competition, 78 Fed. Reg. 68,840 (Nov. 15, 2013) (noting that biologics are "among the most important pharmaceutical products in the United States" and "comprise the fastest growing sector within pharmaceuticals."). In 2010, spending on biologics in the United States was $67 billion, or approximately 20 percent of overall drug spending. IMS Institute for Healthcare Informatics, *The Use of Medicines in the United States: Review of*

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[3] *Amgen Inc. v. Apotex Inc.*, No. 15-61631, slip op. at 2-8 (S.D. Fla. Dec. 9, 2015), appeal docketed, No. 16-1308 (Fed. Cir. Dec. 11, 2015).

[4] *Janssen Biotech, Inc. v. Celltrion Health Care Co.*, No. 15-10698 (D. Mass. Aug. 24, 2015), ECF No. 72; *Amgen Inc. v. Hospira, Inc.*, No. 15-839 (D. Del. Nov. 6, 2015), ECF No. 11.

2010 4, 6 (Apr. 2011).[5] By 2013, spending on biologics in the United States had increased nearly 40 percent to $92 billion, or approximately 28 percent (also a 40 percent increase) of overall drug spending. Alex Brill, *The Economic Viability of a U.S. Biosimilars Industry*, Matrix Global Advisors 4 (Feb. 2015).[6]

On average, biologics cost $45 per day, compared to $2 per day for small-molecule drugs. Steve Pociask, *Lifesaving Drugs at Lower Costs*, American Consumer Institute Center for Citizen Research ConsumerGram 2 (July 22, 2014).[7] Certain biologics cost tens or even hundreds of thousands of dollars per patient per year. For example, Humira®, which treats arthritis and other conditions, costs $50,000/year, and Cerezyme®, which treats Gaucher's Disease, costs $200,000/year. Erwin A. Blackstone and Joseph P. Fuhr, *Innovation and Competition: Will Biosimilars Succeed?* Biotechnology Healthcare, 24-27 (Spring 2012).[8]

The BPCIA's expedited approval pathway allows FDA to approve a biosimilar based on the agency's previous approval of a reference product, thereby both (1) reducing biosimilars' development

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[5]https://www.imshealth.com/files/web/IMSH%20Institute/Reports/The%20Use%20of%20Medicines%20in%20the%20United%20States%202010/Use_of_Meds_in_the_U.S._Review_of_2010.pdf.

[6]http://www.matrixglobaladvisors.com/storage/MGA_biosimilars_2015_web.pdf.

[7]http://www.theamericanconsumer.org/2014/07/new-consumergram-lifesaving-drugs-at-lower-costs/.

[8]http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3351893/.

costs (and therefore their prices) and (2) expediting FDA review, market competition, and patient access to affordable medicines. Increased competition from biosimilars holds the potential for enormous savings for the U.S. healthcare system, with one study estimating savings at more than $44 billion over 10 years. Andrew Mulcahy, Zach Pretmore & Soren Mattke, *The Cost Savings Potential of Biosimilar Drugs in the United States*, RAND Health Advisory Servs. (2014).[9]

B. The BPCIA's Compromise Between Competition and Innovation: 12-Year Exclusivity in Exchange for the Expedited Approval Pathway

The BPCIA represents Congress' carefully-calibrated effort to increase competition in pharmaceutical markets while also preserving incentives to innovate. App. 4a, 87a. To achieve the goal of increased competition, Congress established the expedited biosimilar approval pathway. To achieve the goal of encouraging innovation, and as a *quid pro quo* for the new approval pathway, Congress granted RPS's 12 years of additional statutory exclusivity. 42 U.S.C. § 262(k)(7)(A) (providing that FDA shall not "ma[k]e effective [its licensing of a biosimilar] until the date that is 12 years after the date on which the reference product was first licensed" by FDA). *See also* Thomas M. Burton, *Biosimilar Drugs Face U.S. Test: FDA Panel Will*

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[9] http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

Decide Whether to Recommend Approval, Wall St. J., Jan. 6, 2015, at 2 ("The 2010 Affordable Care Act created an abbreviated pathway for biosimilars to enter the U.S. market . . . . *As a tradeoff for the industry, the law gave biologic drugs a 12-year period of exclusivity that protected them from competition from a biosimilar.*") (emphasis added).[10]

The length of the exclusivity was a particularly hard-fought piece of the overall innovation/competition compromise struck by Congress. The Federal Trade Commission argued that no exclusivity was needed to encourage innovation given patent protections and market pricing incentives, while the Obama Administration supported an exclusivity period of only seven years. Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 787-91 (Nov. 4, 2010). In the end, the 12-year exclusivity was "vetted exhaustively" and was the product of "a genuinely bipartisan Member-level compromise" that was "reached in the summer of 2007 [and] remained intact through three subsequent years of legislative debate" until it "found its place in the final law." *Id.* at 816-17.

C. The BPCIA's "Patent Dance"

As part of Congress' efforts to balance the goals of competition and innovation, the BPCIA contains an extensive, integrated framework, contained in

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[10] http://www.wsj.com/articles/biosimilar-drugs-face-u-s-test-1420590926.

subsection 351(l) (42 U.S.C. § 262(l)), for the resolution of patent disputes between a biosimilar applicant and an RPS.

As a first step in this process, the biosimilar applicant may provide the RPS with its application within 20 days of submission to FDA. 42 U.S.C. § 262(l)(2)(A). If the applicant shares its application, there follows a multi-stage information exchange process – which has come to be known as "the patent dance" – through which the parties can identify patents to be litigated in connection with the proposed biosimilar. This process begins with the parties' exchange of initial patent lists (42 U.S.C. § 262(l)(3)) and can end with a final list that is generated either by agreement of the parties or by following additional steps set forth in subsection 351(l). 42 U.S.C. § 262(l)(4)-(l)(6).

D. The Role of the Notice Provisions in the "Patent Dance"

The notice provisions at issue appear in BPCIA subsection 351(l)(8) (42 U.S.C. § 262(l)(8)) and, as explained in Judge Chen's dissent from the Federal Circuit's decision, are "part and parcel of the integrated litigation management process contemplated in" subsection 351(l). App. 43a. The undisputed purpose of the notice provisions is to trigger the right to litigate immediately, *inter alia*, patents that are included on the preliminary lists exchanged during the "patent dance," but not on the parties' final list. App. 7a (explaining that the notice provisions "allow[] the RPS a period of time to seek a preliminary injunction based on patents that the

parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents (collectively, 'non-listed patents')").[11]

Under 42 U.S.C. § 262(l)(8)(A), a biosimilar applicant provides "notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." And under 42 U.S.C. § 262(l)(8)(B), after receiving notice, the RPS:

> may seek a preliminary injunction prohibiting the [biosimilar] applicant from engaging in the commercial manufacture or sale of the [biosimilar] until the court decides the issue of patent validity, enforcement and infringement with respect to any patent that is –
>
> (i) included in the list provided by the [RPS] under [42 U.S.C. § 262(l)(3)(A)] or in

[11] This two-step litigation process was a compromise intended to allow the biosimilar applicant and the RPS to defer litigation of some patent rights while preserving for the RPS the opportunity to enforce those patents (or newly issued patents) at a later date. Deferral would also potentially benefit a RPS by avoiding a challenge to some of its patent rights at a time when it may be uncertain whether a biosimilar application would be approved, thereby preserving the exclusivity benefit of such patent rights with respect to other potential infringing products (novel or biosimilar).

> the list provided by the [biosimilar] applicant under [42 U.S.C. § 262(l)(3)(B)]; and
>
> (ii) not included, as applicable, on –
>
> (I) the list of patents described in [42 U.S.C. § 262(l)(4)]; or
>
> (II) the lists of patents described in [42 U.S.C. § 262(l)(5)(B)].

In other words, notice provides a safety net that gives the RPS at least 180 days of advance warning of the commercial launch of a biosimilar, so that the RPS can *try* to enjoin the launch on the basis of any patent not already scheduled for resolution as a result of the full "patent dance."

E. The BPCIA'S Express Consequences of Not Providing Notice

The BPCIA's subsection 351(l) integrated patent dispute resolution framework also clearly sets forth the consequences for failure to provide information during each stage of the "patent dance" – including, of particular importance here, the failure to provide notice under subsection 351(l)(8)(A). If, as Petitioner Sandoz did in this case, the biosimilar

applicant declines to take the initial step of providing its application to the RPS, the RPS may initiate patent litigation with respect to *any* patent it deems relevant. 42 U.S.C. § 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii) (adopted as part of the BPCIA as an amendment to the Patent Act). And if the biosimilar applicant fails to complete any of the subsequent steps of the "patent dance" – *including* the step of providing notice – the RPS may initiate patent litigation on any patent contained on the preliminary patent list provided by the RPS under subsection 351(l)(3)(A). 42 U.S.C. § 262(l)(9)(B) (setting forth patent litigation remedy for a biosimilar applicant's "fail[ure] to complete an action required of the . . . applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), *or paragraph (8)(A)* [*i.e.*, the notice provisions]."") (emphasis added)).

F. The Federal Circuit's Decision and Judge Chen's Dissent

In this case, Petitioner Sandoz provided the RPS, Amgen, with notice related to the commercial marketing of Sandoz's biosimilar version of Amgen's product Neupogen® before FDA licensed Sandoz' product (which is known as Zarxio®). Sandoz did not share its application with Amgen pursuant to BPCIA subsection 351(l)(2)(A), thereby permitting Amgen, as it in fact did, to initiate patent litigation with respect to any patent it deemed relevant. 42 U.S.C. § 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

As part of its case against Sandoz, Amgen claimed that notice under the BPCIA had to follow FDA licensure and that Amgen could compel such

post-licensure notice through an automatic injunction. Reversing the district court (App. 73a-76a), the Federal Circuit agreed. App. 18a-26a.[12]

First, the Federal Circuit held that under the plain language of the BPCIA, notice could only be given after FDA licensure of the biosimilar. The Federal Circuit relied on the statute's reference to notice regarding "the product *licensed* under subsection (k)" (App. 19a) (emphasis added), reasoning that because the statute refers to notice of intent to market a biosimilar that has already been "licensed" by FDA, notice itself can only be given after the product is "licensed." App. 19a-23a. The court of appeals added that requiring notice to follow FDA licensure would "ensure[ ] the existence of a fully crystallized controversy regarding the need for injunctive relief." App. 21a.

Second, the Federal Circuit held that post-licensure notice under subsection 351(l)(8)(A) was mandatory and that an RPS like Amgen could compel such notice through a private action for an automatic injunction. App. 23a-26a. The Federal Circuit disagreed that an automatic private injunction conflicted with Congress' chosen remedial scheme for lack of notice under BPCIA subsection 351(l)(9)(C), holding that the notice provisions operated as a "standalone" requirement in cases where, as here, the

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[12] On a separate issue that is not the subject of Sandoz's petition, the Federal Circuit (Judge Lourie, joined by Judge Chen) properly held that the application-sharing provisions in BPCIA subsection 351(l)(2)(A) were not mandatory and that Amgen was therefore not entitled to an automatic injunction forcing Sandoz to provide Amgen with its application for Zarxio®. App. 12a-18a.

biosimilar applicant had not provided its application to the RPS and therefore had failed to trigger the BPCIA "patent dance." App. 25a. The Federal Circuit held that Sandoz could not have given operative notice until March 6, 2015, the date FDA licensed Zarxio®, and was enjoined from marketing its product until 180 days later, on September 2, 2015.

Judge Chen dissented from the majority's conclusion that Amgen could compel notice through an automatic injunction. App. 42a-55a. He explained that notice was not a standalone requirement, but rather "part and parcel of the integrated litigation management process contemplated in [BPCIA subsections 351(l)(2)-(l)(7)]." App. 43a. He further explained that the BPCIA contained an express remedy for lack of notice in subsection 351(l)(9)(B), which allowed an RPS that did not receive notice to initiate immediate patent litigation – not to obtain an "automatic 180-day injunction." App. 52a. Judge Chen added that the practical effect of treating notice as a post-licensure requirement enforceable through an automatic private injunction was to provide the RPS with "an atextual 180-day exclusivity windfall" on top of the BPCIA's express 12-year exclusivity period. App. 53a. *See also* App. 43a ("I do not view (l)(8)(A) as a 'standalone provision' that provides, implicitly, the RPS a 180-day injunction beyond the express twelve-year statutory exclusivity period.")

SUMMARY OF ARGUMENT

The Federal Circuit's decision conflicts with the text, structure and purpose of the BPCIA in three critical respects. First, it blocks patients' access to

affordable medicines for six months longer than Congress intended. Second, it delays resolution of patent disputes between an RPS and a biosimilar applicant until after FDA licensure of the biosimilar. Third, permitting an RPS to compel notice through an automatic private injunction conflicts with Congress' express remedy for lack of notice, as well as with the traditional equitable test for permanent injunctions, from which Congress showed no intention of departing in the BPCIA notice section.

The Federal Circuit's decision, if left uncorrected, would critically undermine Congress' overarching goal of providing patients with swift access to affordable, essential medicines. This Court's review is especially critical at this moment in time, when the biosimilars industry is coming of age and looking to the courts for definitive interpretations of key provisions of the BPCIA that are consistent with, and will advance, the statute's overarching purposes.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's Decision Adds an Extra-Textual 180-Day Windfall to the BPCIA's Express 12-Year Exclusivity, in Conflict with the Statute's Text and Overarching Purposes.

The Federal Circuit's holding that 180-day notice of commercial marketing of a biosimilar is mandatory and can only be effective after FDA licensure of the biosimilar would, as noted by the District Court and Judge Chen's dissent, effectively grant an RPS six additional months of statutory

exclusivity, beyond the 12-year exclusivity period expressly included in the BPCIA. Under the plain terms of the BPCIA and FDA's reading of the statute, FDA cannot finally license a biosimilar until expiration of the exclusivity. 42 U.S.C. § 262(k)(7)(A). *See also* Draft Guidance, FDA, *Guidance for Industry: Reference Product Exclusivity for Biologics Products Filed Under Section 351(c) of the PHS Act* 2 (Aug. 2014) (describing the 12-year exclusivity as "the period of time in which . . . FDA is not permitted to license a [biosimilars application] that references a reference product.")[13] And if the applicant must provide notice but cannot do so until after licensure, as the Federal Circuit held, the 180-day notice period will always add to the 12-year exclusivity.[14] This reading of the BPCIA directly conflicts with both the statute's plain text and with Congress' overall goal of expediting patients' access to needed medicines.

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[13] http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm407844.pdf.

[14] The Federal Circuit suggested that its reading of the notice provisions "does not necessarily conflict with" 12-year exclusivity where (unlike in Sandoz's case) the exclusivity runs concurrent with FDA review of the biosimilar application. App. 22a (noting that the "extra 180 days [of exclusivity] will not likely be the usual case, as [biosimilars applications] will often be filed during the 12-year exclusivity period"). But under the majority's reading of the notice provisions, notice *must* follow FDA licensure. And because licensure *must* in turn follow expiration of the exclusivity, the majority's holding means that notice perforce *must* follow expiration of the 12-year exclusivity and operates to extend that period, regardless of when exclusivity runs.

The Statutory Text

As Petitioner explains (Pet. 23-26), and as the District Court held (App. 73a-76a), the plain text of the notice provisions in no way circumscribes the timing of notice. The Federal Circuit's interpretation of the statute relies exclusively on a flawed reading of the word "licensed" in 42 U.S.C. § 262(l)(8)(A) (which refers to "notice to the [RPS] not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k)" (emphasis added)). The Federal Circuit reasoned that because the statute referred to a biosimilar that had been "licensed" by FDA, the notice itself – not just the product's marketing – had to occur after the biosimilar had been "licensed." App. 20a. But the word "licensed" is clearly intended to modify "the product" that will be commercially marketed, not to limit *the timing* of notice. Congress used the past-tense "licensed" because the right to commercially market a product, regardless of when notice is given, *can only exist after FDA licensure*. In other words, the statute simply provides for notice that the applicant intends to market a biosimilar *once the product has been licensed*, not to set the earliest date notice can be provided. This is the reading adopted by the district court in this case (App. 73a-76a), and it is correct.

This straightforward reading also addresses the Federal Circuit's concern (App. 20a) that Congress did not instead refer in the notice provision to "the biological product that is the subject of the application" under subsection (k). As the District Court explained, a biosimilar that is merely the

"subject of [an] application" *cannot be* commercially marketed, and "[i]t would be nonsensical for [the notice provisions] to refer to a biosimilar as the subject of a subsection (k) application because upon its 'first commercial marketing' a biosimilar must, *in all instances*, be a 'licensed' product." App. 75a (emphasis added).

As the Petition notes (Pet. 23, 25), Congress could have clearly circumscribed the timing of notice by referring to notice "after" FDA licensure or referring to the applicant as the "holder" of an approved application or license. It did not use either of these straightforward formulations, and the language it did use provides no support for the post-licensing condition adopted by the Federal Circuit.

The Overarching Goals of the BPCIA

Even if the statutory text were ambiguous (which it is not), it is inconceivable that Congress intended to disrupt the BPCIA's carefully-crafted exclusivity compromise – and to further delay patients' access to affordable medicines – by adding *sub silentio* six additional months to the express 12-year exclusivity period.

As discussed *supra* p. 6, 12-year exclusivity was a critical, heavily-negotiated piece of the BPCIA's grand compromise between competition and innovation. Congress could not possibly have intended to alter such a key element of this compromise through the indirect means of the BPCIA's notice provisions. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not

alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions – it does not, one might say, hide elephants in mouseholes.") (citations omitted); App. 76a ("Had Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so.") Indeed, when Congress did choose to extend exclusivity beyond 12 years, as it did when the RPS conducts pediatric studies on the reference product, it did so simply and directly. 42 U.S.C. § 262(m)(2)(A) (where pediatric studies are conducted, the 12-year exclusivity "[is] deemed to be 12 years and 6 months rather than 12 years.")

Of course, by its very definition and as Congress intended (subject to the express "pediatric extension"), the statutory 12-year exclusivity period is intended to prevent a biosimilar's launch for 12 years *and no more*. Yet the Federal Circuit's reading of the statute would frustrate this basic congressional policy choice by making the end of the exclusivity period an essentially meaningless event and the end of the notice period 180 days later the true relevant trigger for marketing. A reading of the BPCIA under which notice may be given pre-FDA licensure, so that it does not operate to extend the BPCIA's express 12-year exclusivity period, is the only reading that is consistent with "the whole [BPCIA] and . . . its object and policy." *United States Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (citation omitted). *See also Kokoszka v. Belford*, 417 U.S. 642, 650 (1974) ("When interpreting a statute, the court will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute (or statutes on

the same subject) and the objects and policy of the law, as indicated by its various provisions, and give to it such a construction as will carry into execution the will of the Legislature.") (citation omitted)).

II. The Federal Circuit's Interpretation Also Conflicts with the BPCIA's Goals by Postponing Patent Disputes Until After FDA Licensure of the Biosimilar.

Congress created the BPCIA's integrated patent dispute resolution framework to expedite the resolution of patent disputes – preferably *before* FDA is ready to approve the biosimilar application – as part of its overall goal of making affordable versions of critically important medicines available to patients as soon as possible. App. 45a (noting that BPCIA subsection 351(l) is designed to "lead[] up to the expected patent infringement suit that comes *during the pendency of* a [biosimilars] application" (emphasis added)). Even the trade association for the brand biologics industry, the Biotechnology Industry Association ("BIO"), has acknowledged that the BPCIA is designed "to identify and resolve patent issues *before a biosimilar is approved.*" *Biologics & Biosimilars: Balancing Incentives for Innovation*, Hr'g of Subcomm. on Courts and Competition Policy of H. Jud. Comm., 111th Cong. 77 (2009) (emphasis added).

The notice provisions, aptly described by Judge Chen as "part and parcel" of this framework (App. 43a), serve this goal directly by allowing an RPS to initiate immediate litigation on certain patents that are not part of the final "patent dance" list. 42 U.S.C. § 262(l)(8)(B); App. 7a. But the Federal Circuit's

reading of the notice provisions has the countervailing effect, by postponing notice – and therefore even the initiation, much less resolution, of litigation regarding "unlisted patents" – until *after* FDA approval. Congress cannot have intended this result, which is so plainly contrary to the statute's overall goals and to the patent dispute resolution framework of which the notice provisions are "part and parcel." App. 43a.

Further, as the Petition notes (Pet. 26), notice for the purpose of alerting an RPS to the future marketing of a biosimilar is superfluous in a post-licensure context. FDA licensure is itself a public event that obviates the need for any further notification to the RPS of the biosimilar applicant's plans to go to market. Put another way, the notice provisions should be not be read to achieve an objective to which they are completely unnecessary. *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (noting canon of statutory interpretation that statutes should be read to avoid making any provision "superfluous, void, or insignificant" (citation omitted)).

The Federal Circuit justified its reading of a post-licensing requirement into the notice provisions on the grounds that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." App. 21a. But this explanation misses the point that the entire subsection 351(l) framework – including the notice provisions – is premised on resolution of patent disputes before, and is in no way predicated on, FDA licensure. App. 46a ("Importantly, subsection (l) does not relate to the FDA approval process (for that see

subsection (k)."). No other provision of subsection 351(l) is triggered by FDA licensure, and the notice provisions should not be read differently, outside the context of the statute's overarching goals generally or the patent dispute resolution framework in particular.

III. The Federal Circuit's Extra-Statutory Injunctive Remedy Conflicts with Congress' Chosen Remedial Scheme in the BPCIA and with Traditional Equitable Standards for Injunctions.

"[P]rivate rights of action to enforce federal law must be created by Congress." *Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001) (citation omitted). And where "a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. Nat'l Fed'n of Fed. Empls.*, 489 U.S. 527, 533 (1989) (citation omitted). *See also Alexander*, 532 U.S. at 290 ("The express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others.")

The Federal Circuit's decision runs afoul of these basic tenets. As part of the BPCIA's integrated patent dispute resolution framework, Congress specified that if a biosimilars applicant fails to provide notice under subsection 351(l)(8)(A), the RPS may immediately initiate litigation on any patent on the RPS' original list. 42 U.S.C. § 262(l)(9)(B). This remedy, like the others in BPCIA subsections 351(l)(9)(B) and (C), is patent litigation-based, allowing the RPS to bring patent infringement actions more quickly than would otherwise be possible – all in the service of the statute's overall goal of expediting

access to affordable medicines. In short, Congress expressly chose a procedural mechanism to remedy the failure to provide notice, rather than creating an enforceable substantive right to notice itself.

The Federal Circuit acknowledged the existence of the subsection 351(l)(9)(B) remedy for failure to provide notice, but held that this remedy "does not apply" where, as here, the biosimilars applicant failed to provide its application to the RPS pursuant to BPCIA subsection 351(l)(2)(A). App. 25a. The problem with this analysis is that it does not excuse the Federal Circuit's selection of a remedy that it totally outside of, and inconsistent with, the BPCIA subsection 351(l) framework. It is true that in cases where the biosimilars applicant fails to provide its application, the subsection 351(l)(9)*(B)* remedy is unnecessary because BPCIA subsection 351(l)(9)*(C)* permits an RPS to bring immediate litigation on *any* patent. However, both in cases where the applicant does not even start the "patent dance" because it declines to provide its application *and* in cases where the applicant begins the dance but does not provide notice, Congress provided a patent-litigation based remedy under the BPCIA. In neither case did Congress contemplate the *completely different* remedy – entirely untethered from the BPCIA subsection 351(l) framework – of a private injunction compelling notice. And the courts lack authority to add such a remedy themselves.

The Federal Circuit compounded its error by making available an *automatic* private injunction to compel notice, without regard for the traditional factors governing awards of permanent injunctions.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006) (identifying factors as (1) irreparable injury, (2) inadequate remedies at law, (3) balance of hardships favors an injunction, and (4) public interest favors an injunction). This extra-statutory leap violated this Court's admonition that "a major departure from the long tradition of equity practice," in the form of an automatic injunction, "should not lightly be implied." *Id.* at 395 (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 320 (1982)). Nothing in the BPCIA suggests that Congress intended such a departure in connection with BPCIA notice.

Indeed, the opposite is true. As Judge Chen noted (App. 52a-53a), Congress knows exactly how to use automatic injunctions to delay the marketing of drug products when it wants. In the 1984 Hatch-Waxman law governing small molecule generic drugs, Congress enacted a 30-month automatic stay of FDA's approval of a generic drug application that was the subject of patent litigation, providing that approval "shall be made effective upon the expiration of" the 30-month period. 21 U.S.C. § 355(j)(5)(B)(iii). Congress could similarly have provided in the BPCIA that FDA licensure of a biosimilar "shall be made effective upon the expiration of" the notice period, but it did not do so, signaling its intent not to create an automatic injunction. *Cent. Bank of Denver N.A. v. First Interstate Bank of Denver N.A.*, 511 U.S. 164, 176 (1994) (Congress did not impose aiding and abetting liability under the Securities Exchange Act and its use of "aid" and "abet" in other statutes showed that "Congress knew how to impose aiding and abetting liability when it chose to do so.") (citations omitted)).

Moreover, Congress employed an automatic injunctive remedy *elsewhere* in BPCIA subsection 351(l). 42 U.S.C. § 262(l)(1)(H) (providing for automatic injunction in connection with unwarranted disclosure of confidential information). Congress' express provision for an automatic injunction in a separate part of subsection 351(l) indicates that it did not intend to provide the same remedy in that section in connection with notice. *Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (citation omitted).[15]

This Court "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination" of a statutory violation. *eBay*, 547 U.S. at 392-93 (citations omitted). It should do so again here.

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[15] Amgen could have sought (and could still seek) a preliminary injunction under the normal multi-factor test as part of its patent infringement action against Sandoz under the BPCIA, *see* 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii), but has never done so, trying instead to end-run that process by claiming the right to an automatic injunction under the notice provisions.

IV. This Court's Review and Correction of the Federal Circuit's Erroneous Decision Is Critical to the Continued Growth of the Biosimilars Industry and to the Realization of the BPCIA's Objectives.

The BPCIA stands at a crossroads. Congress created the statute's expedited approval pathway in 2010 with the goal of providing safe, effective alternatives to expensive biologic medicines and thereby helping dramatically cut spiraling health care costs. In just a few years, taking Congress' lead, the biosimilars industry has grown and continues to grow by leaps and bounds (as evidenced by the very existence of the Biosimilars Council). More biosimilars are under development, applications for FDA approval of biosimilars have increased, and agency activity in this area is accelerating. Even Amgen itself has filed a biosimilars application, for a version of the arthritis drug Humira®.

At this early stage of the BPCIA's existence, biosimilars companies, patients, health insurers (both private and government), and other stakeholders are looking to the courts to interpret the statute correctly and conclusively, so that FDA and industry can operate in a settled business environment and Congress' vision of billions of dollars of cost savings for the U.S. healthcare system has the chance of being realized. The Federal Circuit's erroneous interpretation of the BPCIA threatens to broadly undermine Congress' vision and to dramatically reduce anticipated savings to the U.S. healthcare system from biosimilars, just as the industry is coming of age.

This case provides one example of the effect of the Federal Circuit's interpretation: patients were denied access to Petitioner's biosimilar product Zarxio®, an affordable alternative to Amgen's product Neupogen®, until September 3, 2015, even though FDA had approved Petitioner's application six months earlier. But although Zarxio® is now on the market, the Federal Circuit's misreading of the notice provisions will delay patients' access to other biosimilars. Indeed, as noted above, several district courts have followed the Federal Circuit's decision on the notice issue or are currently considering that issue in connection with drugs other than Zarxio®. This Court must step in and provide definitive, correct guidance on this critical issue to the lower courts, to industry, to FDA, and to patients.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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March 21, 2016

AND
BRIEFS,

MAR 2 1 2016
OFFICE OF THE CLERK

No. 15-1039

In the Supreme Court of the United States

SANDOZ INC.,
PETITIONER

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
RESPONDENTS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR HOSPIRA, INC., CELLTRION HEALTHCARE CO., LTD., AND CELLTRION, INC. AS *AMICI CURIAE* IN SUPPORT OF THE PETITION FOR CERTIORARI

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QUESTIONS PRESENTED

Under 42 U.S.C. § 262(*l*)8), whether a notice of commercial marketing must be delayed until after FDA approval and, regardless, whether courts may enforce the notice provision with an automatic, 180-day injunction.

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INTRODUCTION AND INTEREST OF *AMICI CURIAE*

This case involves a critical part of an important statute that the Court has not yet addressed—the Biologics Price Competition and Innovation Act ("BPCIA" or "Act"). The Act creates an expedited path for licensing drugs called biosimilars. Absent review, the Federal Circuit's fractured ruling threatens to cause an unwarranted six-month delay in the marketing of biosimilar medications. Such delay is unsupported by the BPCIA's text or any patent rights of branded biologic makers—who already enjoy 12 years of marketing exclusivity under the Act, independent of any patent protection. Further, delay imposes multibillion-dollar burdens on the nation's health care system and harms those who need low-cost medicine. Given the importance of the issue to consumers, taxpayers, and competition in a vital new pharmaceutical industry, review is needed now.

As their name suggests, biosimilars are biologic drugs similar to branded biologics already licensed by the Food and Drug Administration ("FDA"). The Act says an applicant for FDA approval of a biosimilar product shall notify the brand 180 days before the product is marketed. This "notice of commercial marketing" serves one purpose: It allows the patentee to "seek a preliminary injunction * * * with respect

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* Pursuant to Rule 37.2(a), *amici* provided timely notice of their intention to file this brief. All parties consented, and the letters have been lodged with the clerk. In accordance with Rule 37.6, no counsel for any party has authored this brief in whole or in part, and no person or entity other than the *amici* has made a monetary contribution to the brief's preparation or submission.

to any patent" not yet litigated by the parties—if any such patent exists.

The questions here are whether that notice must be delayed until *after* FDA approval and, regardless, whether courts may enforce the notice provision with an automatic 180-day injunction. In a splintered decision, the Federal Circuit held that notice must be delayed until FDA approves the biosimilar product—regardless of whether the product is otherwise ready for marketing. Further, the court enjoined Sandoz from launching its product until six months after FDA approval, even though Amgen never sought an injunction based on patent rights.

The majority misconstrued the statute as supporting this 180-day injunction, as shown by Judge Chen's powerful dissent and the narrow role of the marketing notice in the larger BPCIA scheme. "Just as Congress' choice of words is presumed to be deliberate, so too are its structural choices." *Univ. of Tex. Sw. Med. Ctr.* v. *Nassar*, 133 S. Ct. 2517, 2529 (2013). The majority below, however, rewrote the BPCIA to award the branded manufacturer (Amgen) an automatic 180-day injunction to the detriment of competition and patients. In so doing, the court distorted the structure of the BPCIA—which is designed to *expedite* patent litigation that might otherwise slow biosimilar competition. The court also ignored the plain instruction of *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006), which reaffirmed that injunctions should ordinarily issue only where supported by equity's traditional four-factor analysis. The Court should grant review and reverse.

Amici and the larger drug industry have a vital interest in this petition. Hospira, a wholly-owned

subsidiary of Pfizer Inc., develops biosimilars, among other pharmaceutical products. Hospira has teamed with Celltrion, Inc., a Korean company that independently develops and manufactures biosimilar antibodies and novel drugs, along with Celltrion Healthcare Co., Ltd., which markets and distributes drugs developed by Celltrion, Inc. in more than 120 countries. *Amici* seek to introduce in the United States Celltrion's biosimilar version of Janssen Biotech, Inc.'s multibillion-dollar drug Remicade® (infliximab) at an affordable cost to patients suffering from debilitating diseases, including rheumatoid arthritis. Janssen sued *amici* under the BPCIA for, among other things, allegedly violating the 180-day notice provision. See *Janssen Biotech, Inc.* v. *Celltrion Healthcare Co., Ltd.*, 1:15-cv-10 (D. Mass.).

Like Amgen, Janssen purports to sue to enforce the notice of commercial marketing provision itself. That is, according to Janssen, *amici* must delay their notice until FDA approval and, with it, their product launch by 180 days—even if no patent rights support injunctive relief. Similar cases are pending throughout the country, and many investment decisions of industry participants await resolution of the question presented. Review is urgently needed.[1]

STATEMENT

The BPCIA created an expedited path for licensing biosimilars of previously-approved biologic medications. Under subsection (k)—which addresses "Licensure of biological products as biosimilar or inter-

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[1] Hospira is litigating a similar dispute against Amgen in *Amgen Inc.* v. *Hospira, Inc.*, 1:15-cv-00839 (D. Del.).

changeable" (42 U.S.C. § 262(k))—the biosimilar applicant may rely on data submitted by a branded biologic drug manufacturer ("sponsor"). In return, the sponsor receives 12 years of marketing exclusivity regardless of whether any patents cover the biosimilar. *Id.* § 262(k)(7)(A).

The petition here focuses on a different portion of the Act, subsection (*l*), which addresses patent rights that could delay marketing. The Federal Circuit conflated these separate subsections by concluding that a paragraph within subsection (*l*) conferred an *additional* 180 days of marketing exclusivity—even though Congress did not say so.

A. Subsection (*l*) creates an optional process to resolve patent disputes.

In enacting the BPCIA, Congress contemplated that a sponsor may have many patents that could be asserted against a given biosimilar application. To resolve such patent rights efficiently, subsection (*l*) of the statute, entitled "Patents," outlines a step-by-step process to determine when litigation as to particular patents may be filed. *Id.* § 262(*l*). Although this detailed patent exchange process—sometimes called the "patent dance"—is not mandatory, Congress imposed consequences for non-participation.

Under the statutory process, neither the sponsor nor the applicant can sue until certain events unfold. At the outset, under paragraph (*l*)(2), the applicant may provide the sponsor with the biosimilar application and information describing the applicant's manufacturing process. *Id.* § 262(*l*)(2)(A). If the applicant does *not* do so (the approach taken by Sandoz), the sponsor—but not the applicant—may bring an immediate declaratory judgment action for patent in-

fringement on patents of its choosing. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

If the applicant *does* provide the information (the approach taken by Celltrion), no one may sue yet. Instead, the sponsor reciprocates by providing a list of patents under which it "believes a claim of patent infringement could reasonably be asserted." 42 U.S.C. § 262(*l*)(3)(A)(i). If the sponsor does not do so, or omits some patents, the sponsor may not sue for infringement of "a patent that should have been included." 35 U.S.C. § 271(e)(6)(C). By penalizing the sponsor for not disclosing relevant patents, the statute encourages disclosure—moving the process along.

If the sponsor provides its patent list, the applicant may provide both a "detailed statement" of its factual and legal contentions for each listed patent and the applicant's own list of patents that reasonably could be asserted. 42 U.S.C. § 262(*l*)(3)(B). Through this information exchange, the BPCIA encourages the parties to agree upon "which, if any, patents" will be the subject of an "action for patent infringement." *Id.* § 262(*l*)(4)(A).

The final list of patents, which may give rise to an "immediate" infringement lawsuit, is determined either by agreement or by following certain steps—thus beginning the first statutory phase of litigation. *Id.* § 262(l)(6)(A),(B); 35 U.S.C. § 271(e)(2)(C). For any patent appearing on the final patent list, if the sponsor sues within 30 days, it may seek the full complement of infringement remedies—including injunctive relief and damages for lost profits. 42 U.S.C. § 262(*l*)(6)(A),(B); 35 U.S.C. § 271(e)(4). But if the sponsor does not file an infringement lawsuit within this 30-day period—or if its suit is "dismissed" or is

"not prosecuted * * * in good faith"—"the sole and exclusive remedy" is a "reasonable royalty." 35 U.S.C. § 271(e)(6)(A), (B).

Congress designed these procedures to resolve patent disputes on key patents first, thus speeding competition. For example, Congress recognized that the threat of a lost-profits award against the applicant could deter it from launching its product. So Congress penalized a sponsor for delaying litigation by barring it from recovering lost profits.

Moreover, nothing in the statute prevents the sponsor from seeking a preliminary injunction on any litigated patents at any time after the lawsuit begins—even when FDA approval is years away. As with any injunction, the only restrictions are the requirements of Article III and satisfying the traditional four-factor test, which considers the strength of the sponsor's claims and the risk of irreparable harm.

B. The 180-day notice under subsection (*l*)(8)(A) relates solely to a potential second litigation phase.

All of this leaves a question of timing: When can the parties litigate any patents that appeared in an initial patent list but were omitted from the final patent list—i.e., "phase-two patents"? Subject to an exception described below, neither the sponsor nor the applicant may sue on these secondary, phase-two patents "prior to the date notice [of commercial marketing] is received under paragraph (8)(A)." 42 U.S.C. § 262(*l*)(9)(A).

The bar on litigating phase-two patents can be lifted in one of two ways. *First*, as discussed in paragraph (*l*)(9)(A), the applicant can provide a notice of commercial marketing. This notice is described in

paragraph (8)(A), which says "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." *Id.* § 262(*l*)(8)(A). If provided, this notice creates a 180-day period during which either the sponsor or the applicant may seek declaratory relief. As explained in paragraph (8)(B), the sponsor may then "*seek* a preliminary injunction * * * with respect to any [phase-two] patent." *Id.* § 262(*l*)(8)(B) (emphasis added). The injunction, therefore, is not automatic.

Second, the statute lifts the bar on litigating phase-two patents if, before the biosimilar launch, the sponsor requests notice of marketing but the applicant refuses. That is, if the sponsor is concerned that the applicant is about to launch (because approval is imminent or exclusivity will soon expire), the sponsor could request that the notice be provided. And if the applicant refuses to provide notice, the sponsor may immediately file a declaratory judgment action and seek an injunction. This can happen, for example, when FDA announces public hearings as to the biosimilar application. In that instance, the "sponsor, but not the subsection (k) applicant," may file an immediate declaratory judgment action on any phase-two patents. *Id.* § 262(*l*)(9)(B) (emphasis added). By referring to a "declaratory judgment action," as opposed to an "action for patent infringement," Congress contemplated litigation *before* actual infringement—that is, before the applicant launches its product.

In short, the marketing notice serves a limited purpose: It allows the sponsor, after receiving the notice, to "seek" an injunction based on any phase-two

patents. *Id.* § 262(*l*)(8)(B). Indeed, the notice serves no statutory purpose if either: (1) there are no phase-two patents (a common scenario, as discussed below); or (2) the bar on litigating phase-two patents otherwise has been lifted (e.g., because the applicant refuses to provide notice). The notice is not a requirement for FDA approval. Nor does it guarantee the sponsor market exclusivity, much less an automatic 180-day injunction.

C. The majority below invokes the notice provision to enjoin Sandoz from marketing for 180 days after FDA approval, regardless of patent rights.

In this case, the biosimilar applicant (Sandoz) refused to produce its application and manufacturing information in a timely manner, arguing that the statute does not require such production. App. 8a. Amgen sued for injunctive relief to enforce the (*l*)(2) disclosure requirements and the paragraph (*l*)(8) notice provision, but the district court denied that request. Amgen appealed and sought an injunction pending appeal under the traditional four-factor test. The Federal Circuit granted the injunction (App. 19a) and, in a split decision, addressed three issues of statutory interpretation (the latter two are the subject of Sandoz's petition).

First, a majority held that paragraph (*l*)(2)(A)—which says the biosimilar applicant "shall provide" its application within the prescribed 20-day timeframe—is not mandatory. The BPCIA's "'shall' provision," the court observed, "cannot be read in isolation," as Congress later "specifically sets forth the consequence" for failing to disclose the application on time. App. 15a. Under that statutory remedy, "the [spon-

sor] may bring an infringement action" right away—the same remedy provided to the sponsor when the applicant fails to provide a notice of commercial marketing. *Ibid.* Because "the BPCIA explicitly contemplates that a subsection (k) applicant might fail" to provide its application in a timely manner, and "specifically sets forth the consequence for such failure," it follows that "'shall' * * * does not mean 'must.'" *Ibid.* Otherwise, "mandating compliance [with the 'shall' provision] in all circumstances would render [the consequence provisions] superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous." App. 17a.

Second, the court "conclude[d] that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product." App. 20a. As a result, Sandoz's notice provided before FDA licensure was deemed ineffective.

Third, a majority found the notice mandatory as to Sandoz and entered a 180-day injunction. The court found that "[p]aragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*)"—that is, "nothing in subsection (*l*) excuses [Sandoz] from its obligation to give notice of commercial marketing to [Amgen] after [Sandoz] has chosen not to comply with paragraph (*l*)(2)(A)." App. 25a. The court acknowledged the statutory remedy for noncompliance with the notice provision in paragraph (*l*)(9)(B), but found that it "does not apply" because "Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." *Ibid.*

In entering the injunction, the court did not directly address whether Amgen showed irreparable

harm to support injunctive relief. Instead, it merely referred to its earlier order that summarily granted an injunction pending appeal: "In light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended through September 2, 2015." App. 19a.

Judge Chen dissented from the injunction order. He explained that allowing the sponsor to bring an immediate declaratory judgment lawsuit for infringement—the remedy in paragraph 9 for either failing to provide the application, or failing to provide the marketing notice—eliminated any need for injunctive relief. That is, once the sponsor may bring "an unrestricted patent infringement action," the bar on filing suit disappears, and the notice serves no purpose. App. 51a.

As Judge Chen further explained, "[t]he practical consequence of the majority's interpretation is that (*l*)(8)(A) provides an inherent right to an automatic 180-day injunction. The majority provides no basis in the statutory language to support this automatic injunction." App. 52a. He continued: "If Congress intended to create a 180-day automatic stay it understood how to do so. It could have tied FDA approval to the notice provision. Yet, Congress declined to link FDA approval to a single provision in subsection (*l*). At bottom, the majority's view is in tension with the defined purpose of (*l*)(8) while providing the [sponsor] with an atextual 180-day exclusivity windfall." App. 52a–53a.

Judge Chen's windfall prediction proved correct. As expected, Amgen never sought a preliminary in-

junction during the 180-day period. Instead, it enjoyed its judicial reprieve from competition, which had nothing to do with patent rights. In the meantime, cancer patients had to wait an additional six months after FDA approval for their lower-priced drug provided by competition.

REASONS FOR GRANTING THE WRIT

I. Review is needed to prevent pointless, 180-day injunctions untethered to patent rights or regulatory exclusivity.

It is undisputed that Amgen never sought an injunction to protect any patent rights during the 180-day injunction period here. Yet Amgen convinced the majority below to block cancer patients from receiving a lower-priced (and potentially life-saving) product for this entire period *solely* on the ground that the BPCIA forbade such marketing. The majority offered no congressional rationale for this result, much less an explanation for why Congress would have created such a six-month exclusivity period via the convoluted method of a mandatory notice triggered by FDA approval, followed by an implied right to an automatic injunction. That notion is foreclosed by the Act's text and structure, as well as this Court's precedents. Moreover, the ruling has implications for every case arising under the BPCIA, warranting immediate review.

A. The panel never explained why Congress would have bestowed six months of windfall exclusivity.

1. By its terms, the BPCIA's notice requirement does not create an automatic injunction regardless of patent rights; it describes when the sponsor may

"*seek* a preliminary injunction * * * *with respect to any patent*." 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). Thus, if the sponsor has no "injunction" to "seek" on "any patent," it certainly lacks any basis for receiving an automatic, 180-day injunction.

After all, the subsection is entitled "Patents," and the notice provision is entitled "Notice of commercial marketing and preliminary injunction." Given this plain language, Congress surely did not intend to award an injunction divorced from "[p]atents."

Confirming this conclusion, the statute provides that no "action * * * for a declaration *of infringement* * * * *of any patent*" may occur "prior to the date notice is received." *Id.* § 262(*l*)(9)(B) (emphasis added). Conversely, if the applicant "fails to complete" the "action required under * * * paragraph (8)(A)"—i.e., if it fails to send the notice of commercial marketing—the "sponsor * * * may bring an action * * * for a declaration *of infringement* * * * *of any patent*." *Id.* § 262(*l*)(9)(B) (emphasis added). In both cases, the BPCIA provides for an injunction only if tied to a showing of patent infringement.

Indeed, this is the only rationale the majority gave for requiring the marketing notice "after FDA licensure"—namely, to "allow[] the [sponsor] to effectively determine whether, and on which patents, to seek a preliminary injunction." App. 21a. Amgen said the same thing below, "explain[ing] that giving notice after FDA licensure provides time for the [sponsor] * * * to resolve patent disputes." App. 19a. As the majority summed things up, "[t]he purpose of paragraph (*l*)(8)(A) [is] clear: requiring notice of commercial marketing * * * to allow the [sponsor] a period of

time to assess and act upon its patent rights." App. 25a-26a.

In short, everybody agrees that the marketing notice exists to trigger injunction litigation resolving any remaining patent rights. Where, as here, the sponsor presses no patents that could support such an injunction, no injunction is authorized. Review is needed to make that clear, and to prevent windfall injunctions like the one entered below—injunctions that will cost taxpayers billions of dollars.

2. Precisely because the BPCIA ties the marketing notice to "patent rights," it also makes no sense to tie the notice to FDA approval—which has nothing to do with patent rights. Subsection (*l*) is entitled "Patents" and concerns patent litigation, not regulatory exclusivity. Nor is the FDA approval process contingent on the marketing notice. Thus, there is no purpose in delaying this notice, which merely triggers any phase-two litigation, until FDA approval. As the petition shows, a host of textual indicators confirm this conclusion. Pet. 23-27. But consider, in particular, paragraph (*l*)(7).

This paragraph, entitled "Newly issued or licensed patents," explains what to do when a patent "is issued to * * * the [sponsor] after * * * the [sponsor] provided the list to the * * * applicant[.]" 42 U.S.C. § 262(*l*)(7)(A). In that case, where the "sponsor reasonably believes that * * * a claim of patent infringement could be reasonably asserted[,]" the sponsor "shall * * * provide to the [applicant] a supplement to the list * * * *and such patent shall be subject to paragraph (8).*" *Id.* § 262(*l*)(7)(B) (emphasis added). Paragraph 8 is the marketing notice requirement. Thus, under paragraph (*l*)(7), a newly issued patent cannot

be litigated right away; it must await the marketing notice—which, under the decision below, must await FDA approval. Thus, under the majority's reasoning, the parties must wait to litigate newly issued or licensed patents until after FDA approval.

This interpretation makes no sense. Suppose the parties begin phase-one patent litigation in year 5 of the 12-year marketing exclusivity and conclude that litigation in year 8. But then in year 9, while the parties await FDA approval, a new patent may issue. Under the decision below, the parties must sit on their hands for 3 years waiting for FDA approval before they can even *begin* to litigate the new patent.

Why? Because, again, under paragraph (*l*)(7), "such patent shall be subject to paragraph (8)" (*ibid.*)—that is, the notice requirement. And that notice, according to the opinion below, cannot validly be sent until FDA approval. The majority's reading thus delays litigation for no apparent purpose.

Indeed, the majority itself acknowledged this result: "Subsection 262(*l*) also provides that the applicant give notice of commercial marketing to the [sponsor] at least 180 days prior to commercial marketing of its product licensed under subsection (k), which then allows the [sponsor] a period of time to seek a preliminary injunction *based on * * * any newly issued or licensed patents*. App. 7a (emphasis added). Why would Congress require the parties to wait until FDA approval to begin litigating new patents? The majority never directly addresses this question. Under a proper reading of the statute, notice may be given even if FDA approval is years away.

3. The majority posits that "[r]equiring that a product be licensed before notice of commercial mar-

keting ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." App. 21a. But this rationale does not make sense.

First, the statute itself contemplates that the vast majority of patents (i.e., those litigated in phase one) will be fully addressed years before FDA approval. *Ibid.* The Act authorizes patent litigation seeking permanent injunctions to begin after year four of the 12-year exclusivity. Thus, Congress obviously contemplated that this litigation would be completely resolved by the end of year 12. 42 U.S.C. §§ 262(k)(7) & (*l*)(6), (9). Subject to the limitations of Article III, and as with litigation under the Hatch-Waxman Act, Congress considered these disputes to be "fully crystallized" before FDA approval.[2]

Second, the majority misconstrues the purpose of the notice, which, as discussed, addresses only phase-two patents—to the extent any exist. Phase-two patent disputes are no less capable of being "fully crystallized" before FDA approval than phase-one disputes. A patent is relegated to phase-two status because the parties decided to postpone that particular dispute, not because the dispute was not ripe. *Supra* at 4-8. Thus, delaying the notice of commercial marketing until FDA approval accomplishes nothing—other than to provide sponsors with windfall protection from competition. *Supra* at 11-13.

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[2] Moreover, courts have routinely entertained preliminary injunction motions even though the generic drug manufacturer was merely seeking FDA approval. See, *e.g.*, *Glaxo Group Ltd.* v. *Ranbaxy Pharms, Inc.*, 262 F.3d 1333, 1338 (Fed. Cir. 2001); *The Research Found.* v. *Mylan Pharm. Inc.*, 723 F. Supp. 2d 638, 644 (D. Del. 2010).

4. Third, the majority's reading is in tension with the language of § 262(*l*)(8)(A) directing that notice be provided "not later than 180 days before the date of the first commercial marketing." The phrase "not later than" confirms that Congress wished to encourage early notice while giving applicants flexibility on timing. But for applicants that have already succeeded in preparing their products for market by FDA approval—an endeavor that may take a decade and hundreds of millions of dollars—the majority below effectively read the statute to provide that notice be provided "not *sooner* than 180 days before" commercial marketing.

This turns the Act's incentive structure on its head. The majority took language designed to expedite biosimilar competition and rewrote it to delay competition—to the detriment of consumers needing lower-cost medicines. Review is warranted.

B. Congress created no private right to enforce the notice requirement, and an automatic injunction would violate *eBay*.

1. Compounding its error, the majority inexplicably sidestepped Sandoz's argument that Congress never created a private right to seek injunctive relief to enforce the 180-day notice. See C.A. No. 15-1499, *Amgen Inc.* v. *Sandoz Inc.*, Dkt. 69 at 49-54. As this Court has repeatedly emphasized, "courts should not create liability * * * where Congress has elected not to." *E.g.*, *Limelight Networks, Inc.* v. *Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 (2014). "When Congress intends private litigants to have a cause of action to support their statutory rights, the far better course is for it to specify as much when it creates those rights." *Cannon* v. *Univ. of Chicago*, 441 U.S. 677, 717 (1979)

(emphasis added). As Congress here created no claim for the injunction entered below, it should be vacated.

Although the BPCIA confers a private right to seek declaratory relief as to patent rights if the applicant refuses either to participate in the patent exchange or to provide the 180-day notice (42 U.S.C. §§ 262(*l*)(9)(B), (C)), the Act does not confer a private right to enforce the notice provision. There certainly is no express right, as Amgen conceded in not alleging a private right of action under the BPCIA but, instead, seeking to enforce California law. App. 9a; Oral Arg. Tr. 16:3-6, *Amgen, Inc.* v. *Sandoz, Inc.*, No. 3:14-cv-04741 (N.D. Cal. Mar. 13, 2015).

Further, the standard for implying a private right of action is strict: Courts must ask whether the statute "displays an intent to create not just a private right but also a private remedy." *Alexander* v. *Sandoval*, 532 U.S. 275, 286 (2001). Absent such intent, "a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-287.

There is no evidence that Congress intended to create a private right of action to enforce paragraph (*l*)(8)(A). Indeed, the BPCIA provides the remedy for failing to provide the 180-day notice—an immediate declaratory judgment action (the same remedy the majority below found barred an injunction to compel compliance with paragraph (*l*)(2)). 42 U.S.C § 262(*l*)(9)(B); App. 12a-18a. And "[t]he express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." *Sandoval*, 532 U.S. at 290. It is "elemental" that where a statute provides a remedy, courts must be

"especially reluctant to provide additional remedies." *Karahalios* v. *Nat'l Federation of Federal Empl., Local 1263*, 489 U.S. 527, 533 (1989).

Had Congress intended to create a different private right of action authorizing an automatic 180-day injunction here, it could have said a court "shall order an injunction," or at least "consider immediate injunctive relief." But while Congress used this precise language elsewhere in the BPCIA, it used no such language in paragraph (*l*)(8).

Specifically, when adopting the BPCIA, Congress provided that, "[f]or an act of infringement, * * * [*t*]*he court shall order a permanent injunction* prohibiting any infringement of the patent by the biological product" under circumstances not relevant here. 35 U.S.C. § 271(e)(4) (emphasis added). Elsewhere, Congress provided that the unauthorized disclosure of confidential information "shall be deemed to cause [the applicant] to suffer irreparable harm," and thus "the court *shall consider immediate injunctive relief.*" 42 U.S.C. § 262(*l*)(1)(H) (emphasis added). In short, Congress knew how to address injunctive relief in the BPCIA when it wanted to—whether by commanding that "the court shall order" or "shall consider" an injunction. Here it did neither. And "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally." *Russello* v. *United States*, 464 U.S. 16, 23 (1983) (quotation omitted).

Similarly, Congress created a private counterclaim in the Hatch-Waxman Act, which contains "certain similarities in its goals and procedures" to the BPCIA. App. 5a. Specifically, 21 U.S.C.

§ 355(j)(5)(C)(ii)(I) authorizes "a counterclaim seeking an order requiring the [brand] to correct or delete [certain] patent information" submitted to the FDA. See generally *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670 (2012). Thus, Congress knows how to create a private right of action and remedy in this arena, yet it chose not to do so to enforce the 180-day notice provision.

Instead, subsection (*l*) of the BPCIA creates a streamlined process to allow biosimilar applicants and sponsors to determine which patents should be litigated, and when. Congress also created a remedy for any failure to act under subsection (*l*)—namely, the right to sue immediately. Viewing the BPCIA framework as a whole, it is plain that Congress created no private right of action to enforce compliance with paragraph (*l*)(8)(A), much less to obtain an automatic 180-day injunction. Insofar as a private right of action is needed to enforce the patent disclosures and exchange provisions of the BPCIA, it is the responsibility of Congress, not the courts, to create one. *E.g.*, *3M* v. *Barr Labs., Inc.*, 289 F.3d 775, 777 (Fed. Cir. 2002); *Mylan Pharms, Inc.* v. *Thompson*, 268 F.3d 1323, 1332 (Fed. Cir. 2001).

Ultimately, Amgen's claim for a 180-day injunction fails because paragraph (8)(A) contains no "rights-creating language" entitling it to bring a private right of action to enforce the 180-day notice provision, as opposed to its patent rights. See *Alexander*, 532 U.S. at 288 (quotation omitted); *Touche Ross & Co.* v. *Redington*, 442 U.S. 560, 571–576 (1979) ("[I]mplying a private right of action on the basis of congressional silence is a hazardous enterprise, at best."). Far from it: Subsection 262(*l*) of the BPCIA,

entitled "Patents," merely provides a framework to help the parties address patent disputes efficiently.

2. In any event, even if Congress implied a private right of action to enforce the BPCIA's notice provision, it still would be inappropriate to enter what is, in effect, an *automatic* 180-day injunction as a remedy for failure to provide the notice. This is particularly true where, as here and in *amici*'s case, the notice serves no statutory purpose.

Nothing in the BPCIA alters the longstanding rule that "whether to grant or deny injunctive relief rests within the equitable discretion of the district courts," or that "such discretion must be exercised consistent with traditional principles of equity." *eBay Inc.*, 547 U.S. at 394. Moreover, this Court "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows" a statutory violation. *Id.* at 392–393. How could the sponsor be irreparably harmed absent the 180-day injunction if the sponsor has no intent to seek an injunction based on patent rights? The majority avoided that question entirely.

Certiorari should be granted to confirm that there is no private right of action to enforce the notice provision or, alternatively, that an injunction may issue only if necessary to protect patent rights and only if the patentee first satisfies *eBay*.

II. Review is needed to close the three-way split in the decision below and set the competitive framework for the biosimilars industry.

How to read the BPCIA's marketing notice provision is an important question under Rule 10, and the Court should not allow the issue to "percolate" merely

because the question is one of "first impression." Pet. 3a. The panel split on the key question regarding injunctive relief, and the Federal Circuit declined to grant en banc review—even though all three judges called the question a "riddle" and an "enigma" (App. 4a, 54a), and even though the majority's decision threatens to undermine the competition that Congress expected to "save government and private payors tens of billions of dollars." Pet. 3. Resolving this question is vital to the functioning of the growing, multibillion-dollar biosimilars industry. The provision at issue is a key element of a significant statute governing an industry at the vanguard of health care delivery in the 21st Century. And the Federal Circuit's decision is already being misused in lower courts to stymie Congress's goal of promoting biosimilar competition. Pet. 41.

For example, in its dispute with *amici*, Janssen argues that notice of commercial marketing requires an automatic 180-day injunction even though, unlike here, Celltrion timely provided its aBLA. Janssen thus seeks to expand the ruling below to authorize an automatic 180-day injunction following FDA approval for *all* sponsors. This issue affects the whole industry, warranting review of the notice provision.

These and other "pending cases" (Pet. 41) underscore the need for this Court's review. "Because the Federal Circuit has exclusive jurisdiction over appeals from all United States District Courts in patent litigation, the rule that it applied in this case * * * is a matter of special importance to the entire Nation." *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993). Review is all the more appropriate in light of the splintered decision below. See, *e.g.*, *United States* v. *Tohono O'Odham Nation*, 563 U.S. 307, 310

(2011) (granting review of a decision by a "divided panel of the * * * Federal Circuit"); *Microsoft Corp.* v. *AT & T Corp.*, 550 U.S. 437, 447 (2007) (same); *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 201 (2005) (same).

This Court has not hesitated to take up similar questions under the Hatch-Waxman Act, where those questions were critical to the incentives and competitive frameworks created by Congress. In *Eli Lilly & Co.* v. *Medtronic, Inc.*, 872 F.2d 402, 404 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990), the Federal Circuit decided a "question of first impression, namely, whether the noninfringement defense of 35 U.S.C. § 271(e)(1) * * * applies to medical devices." But that did not deter this Court from granting certiorari, presumably because a circuit-split was impossible, and a definitive ruling was needed.

Similarly, *Caraco Pharm. Labs.* v. *Novo Nordisk*, 601 F.3d 1359 (Fed. Cir. 2011)—which likewise produced three opinions below—was the Federal Circuit's first occasion to address whether the Hatch-Waxman Act's counterclaim provision authorized generics to contest the accuracy of patent information that brands submit to FDA. Again, this Court did not delay in taking up the matter, presumably because the counterclaim was vital to "facilitat[ing] the approval of generic drugs as soon as patents allow." 132 S. Ct. at 1676. Here, the issue is also vital to facilitate new drugs and foster competition.

Even outside the intellectual property context, this Court has often reviewed important statutory questions of first impression. Thus, in *United States* v. *Donovan*, this Court "granted certiorari to resolve * * * issues [that] concern the construction of a major

federal statute." 429 U.S. 413, 422 (1977); see also *Am. Fed. of Musicians* v. *Wittstein*, 379 U.S. 171, 175 (1964) ("grant[ing] certiorari" where the question presented was "an important one of first impression under the [statute]").

Likewise, this Court reviews cases that "raise[] questions of importance in the administration of the [statute]." *United States* v. *Ruzicka*, 329 U.S. 287, 288 (1946); see also *Nat'l Broiler Mktg. Ass'n* v. *United States*, 436 U.S. 816, 820 (1978) ("Because of the importance of the issue for the [business] community and for the administration of the [statute], we granted certiorari."); *Rothensies* v. *Elec. Storage Battery Co.*, 329 U.S. 296, 299 (1946) ("The gravity of this holding to the administration of the [statute] led us to grant certiorari.").

All of these reasons call for review here, especially as Congress plainly sought to enable brand and generic drug makers to resolve their disputes quickly—thus expediting competition that benefits patients. Review is needed now.

CONCLUSION

For the foregoing reasons, certiorari should be granted.

Respectfully submitted.

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MARCH 2016

RECORD AND BRIEFS

No. 15-1039

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* MYLAN INC. IN SUPPORT OF THE PETITION FOR CERTIORARI

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INTEREST OF THE *AMICUS CURIAE*[1]

Mylan Inc. ("Mylan") is a global pharmaceutical company and one of the world's leading generics and specialty pharmaceutical companies. Mylan, through its subsidiaries (collectively, "Mylan"), has filed hundreds of approved Abbreviated New Drug Applications for generic small-molecule drugs, and offers a growing portfolio of more than 1,400 generic pharmaceuticals and several brand medications. With sales in approximately 165 countries and territories, Mylan is dedicated to providing greater access to high-quality, lower-priced medicines.

Mylan also has a robust pipeline of biologic products in development, both for the global marketplace and to be submitted for licensure in the United States as biosimilar products under the Biologics Price Competition and Innovation Act ("BPCIA"). Mylan is committed to providing patients expanded, and timely, access to high-quality and affordable biopharmaceuticals.

Mylan thus has a significant interest in the proper interpretation and application of the BPCIA, including ensuring that the BPCIA is not misused to create extra-statutory remedies, or misinterpreted to

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[1] All parties have consented to this filing. Correspondence reflecting the parties' consent has been lodged with the Clerk. No counsel for any party authored this brief in whole or in part. No party, counsel for any party, or person other than *amicus curiae* or its counsel made a monetary contribution to the preparation or submission of this brief.

create de facto exclusivities for Reference Product Sponsors ("RPS") contrary to Congressional intent, thereby delaying competition and consumer access to less expensive medicines.

SUMMARY OF ARGUMENT

The BPCIA reflects a careful and critical balance between innovation and price competition. On one side, Congress created an abbreviated licensure pathway that allows applicants to file a so-called abbreviated biologics licensure application ("aBLA") under 42 U.S.C. § 262(k) for biological products shown to be biosimilar to, or interchangeable with, a licensed reference product. In exchange, Congress granted RPSs certain periods of exclusivity which prevent applicants from filing an aBLA for a biosimilar product for four (4) years from the date the reference product was licensed, and which delay ultimate eligibility for licensure of an aBLA product for 12 years from the date the reference product was licensed. The Federal Circuit's decision ignores this critical balance and effectively extends the reference sponsor's 12-year exclusivity period by 180 days *every time* an aBLA applicant gives notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A). The Federal Circuit's interpretation of Section 262(*l*)(8)(A) cannot stand—and should be immediately reviewed by this Court—because it converts a simple notice provision into a de facto 180-day extension of market exclusivity, and provides for an automatic 180-day preliminary injunction against every biosimilar sponsor with no consideration of the merits or equities.

Not only is immediate review necessary to ensure that the balance struck by the BPCIA is respected, the Federal Circuit's interpretation is simply wrong. The Federal Circuit ruled that the notice provision under Section 262(*l*)(8)(A) is a mandatory stand-alone provision, enforceable by an RPS like Amgen, under which an aBLA applicant like Sandoz, here, must wait to give notice of commercial marketing until *after* licensure. This interpretation fails on several levels. For one, only Congress can create a private right of action to enforce federal law, and it did not do so here. Adding to that, the Federal Circuit's decision is contrary to the express statutory language and goals of Congress, which established a statutory mechanism to facilitate early *pre*-licensure patent resolution. The Federal Circuit's decision is based on reasoning that reflects a fundamental misunderstanding of the detrimental impact it will have on all future aBLA applicants for years to come. And the Federal Circuit's decision ignores clear precedent from this Court by creating an automatic 180-day preliminary injunction against biosimilar sponsors without regard to the traditional requirements for equitable relief.

The Federal Circuit's decision not only hurts aBLA applicants—who must wait 180 days to market their products even after they have demonstrated biosimilarity to the relevant licensed reference products and all statutory exclusivities have expired, but also consumers and payers—who are forced to wait an extra six (6) months for a competing product to enter the market and drop

prices. These costs capsize the balance Congress sought so hard to create.

Review is particularly appropriate here because the reach of the Federal Circuit's decision is not limited to the facts of this case. While Sandoz, in this case, elected not to disclose its filgrastim aBLA to Amgen or participate in the patent exchange process set forth in Section 262(*l*) (the so-called "patent dance"), the Federal Circuit's decision already has been applied in at least one other biosimilar case involving an aBLA applicant that *did* disclose its application and participate in the patent dance. Thus, the Federal Circuit's decision has the potential to delay the market entry of *every* aBLA product by at least 180 days after licensure.

Mylan urges this Court to grant Petitioner's request and review the Federal Circuit's decision, to restore the balance Congress created and immediately correct the Federal Circuit's erroneous and costly misunderstanding and misapplication of the BPCIA while the Act is still in its infancy.

ARGUMENT

I. THIS CASE PRESENTS AN OPPORTUNITY FOR THIS COURT TO CORRECT THE FEDERAL CIRCUIT'S FUNDAMENTAL MISUNDERSTANDING OF THE BPCIA AND PREVENT THE UNINTENDED CONSEQUENCES OF MANDATORY POST-LICENSURE NOTICE.

The issues raised by Petitioner are critical to the proper application of the BPCIA and operation of the biosimilars industry as a whole. Under the Federal Circuit's decision, an RPS may privately enforce the notice provision of the BPCIA and effectively extend the RPS's statutory market exclusivity for 180 days longer than Congress intended *every time* notice is given or required to be given. This result, as Petitioner has explained, and as discussed further below, has no basis in the statute and, in fact, squarely conflicts with one of Congress's primary goals in creating the BPCIA—the establishment of an early patent dispute mechanism for the RPS and aBLA applicant. If certiorari is not granted, the Federal Circuit's flawed statutory interpretation will remain unchecked and will be applied by courts throughout the country; RPSs will benefit from an extra-statutory windfall that Congress never intended; and patients and biosimilar companies will suffer from delayed entry of more affordable biologic products.

At the heart of the Federal Circuit's decision is a fundamental misunderstanding of the practical consequences of requiring notice *after* licensure but

before commercial marketing. In an attempt to downplay the anti-consumer effects of its decision, the Federal Circuit asserts "[t]hat [the] extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." App. 22a. But this statement misunderstands, if not completely ignores, the timing consequences of mandating post-licensure notice of commercial marketing. Because licensure cannot occur until the RPS's 12-year exclusivity expires, the Federal Circuit's decision requiring notification after licensure inevitably and effectively extends this market exclusivity in *all* instances where notice is given.

At least one district court in Florida already has blindly adopted and extended the Federal Circuit's interpretation, and the reasoning behind it, beyond the situation when an aBLA applicant elects not to disclose its aBLA or participate in the patent exchange process. In holding that notice after licensure is required even when an aBLA applicant has disclosed its application and manufacturing information and engaged in the patent exchange process, the district court latched onto the Federal Circuit's misunderstanding of how often biosimilar marketing would be delayed, and assumed, as the Federal Circuit did, that such a result will not necessarily occur when aBLA applicants file their applications during the 12-year exclusivity period. *See Amgen Inc. v. Apotex Inc.*, No. 15-cv-61631, slip op. at 6-7 (S.D. Fla. Dec. 9, 2015), appeal docketed, No. 16-1308 (Fed. Cir. Dec. 11, 2015). This example places into sharp focus the need for immediate review

to correct the Federal Circuit's error and to ensure that this mistake is not perpetually carried over from court to court, thereby denying the public timely access to lower-priced biosimilars.

Indeed, RPSs are currently exploiting the Federal Circuit's error in BPCIA actions in Massachusetts and Delaware over biosimilar versions of Janssen's Remicade® (infliximab) and Amgen's Epogen® (epoetin alfa) products, respectively. *See Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-cv-10698 (D. Mass. filed Sept. 18, 2015); *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839 (D. Del. filed Mar. 6, 2016). The Federal Circuit's decision also raises the prospect of gamesmanship in future proceedings, in which RPSs will likely seek to improperly extend exclusivity to the detriment of patients in need of lower-priced biosimilar medicines.

The judicial creation of a 180-day de facto exclusivity period disrupts the BPCIA's complex and careful statutory bargain. Congress granted reference products 12 years of exclusivity regardless of patent protection, in exchange for the biosimilar applicant's reliance on the safety and efficacy of the reference product. *See* 42 U.S.C. § 262(k)(7)(A). As Judge Chen aptly pointed out in his dissent, mandatory post-licensure notice gives the RPS "an extra-statutory exclusivity windfall" or, put differently, "an inherent right to an automatic 180-day injunction." App. 44a, 52a (Chen, J., dissenting). But, as Judge Chen acknowledged, if Congress had wanted to create an automatic stay of approval, it knew how to do so. *Id.* at 52a-53a; *see, e.g.*, 21 U.S.C. § 355(j)(5)(B)(iii) (thirty-month stay provision under

Hatch-Waxman). And when Congress wanted to grant additional periods of exclusivity, it *expressly* granted them. *See, e.g.*, 42 U.S.C. § 262(m)(2)(A) (granting "12 years and 6 months" of non-patent exclusivity to sponsors providing pediatric data); 21 U.S.C. § 360cc (granting seven (7) years of non-patent exclusivity for orphan drugs). It did neither here.

Another inherent (and unaddressed) problem with the Federal Circuit's decision is that, under its interpretation, an aBLA applicant's launch will necessarily be delayed by 180 days *regardless* of whether there are patents in dispute at the time notice is given. Indeed, it could easily be the case that, by the time an aBLA applicant is eligible for licensure, all relevant patents have expired, or such patents have already been fully litigated and all disputes resolved. This is a real possibility as more and more future aBLAs are filed immediately after the four (4)-year data exclusivity period expires, where the parties have up to eight (8) years to resolve disputes over the RPS's patents before the aBLA may be eligible for licensure.

This case presents an ideal opportunity for this Court to resolve a critical issue of first impression, while the BPCIA is still in its infancy and the impact of the Federal Circuit's erroneous decision is relatively limited. The Federal Circuit has denied rehearing *en banc*, and no other court of appeals is likely to hear these issues as the interpretation of the notice provision is tied directly to the patent resolution regime created under the BPCIA, and the Federal Circuit has exclusive appellate jurisdiction over patent infringement claims and disputes. 28

U.S.C. § 1295(a)(1). If the decision below stands, patient access to biosimilars will always be unnecessarily delayed by 180 days—regardless of patent protection—and the Federal Circuit's mistaken view of the far-reaching detrimental impact of its decision will stand uncorrected.

II. THE FEDERAL CIRCUIT'S DECISION IS WRONG ON THE MERITS.

A. The Federal Circuit Has Created A Private Right Of Action That Does Not Exist, In Violation Of Clear Supreme Court Precedent.

Under a plain reading of the statute, Section 262(*l*)(8)(A) is not a stand-alone notice provision that can be privately enforced. The Federal Circuit improperly fashioned a private right of action to enforce compliance with this provision—ignoring the settled rule, repeatedly affirmed by this Court, that "private rights of action to enforce federal law must be created by Congress." *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). This Court should grant review to correct this judicial overreaching.

This Court has recognized "where the text and structure of a statute provide no indication that Congress intends to create new individual rights, there is no basis for a private suit . . . under an implied right of action." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 286 (2002). Here, there is no evidence that Congress intended for an RPS to compel compliance with the notice provision through the extra-statutory injunctive relief created by the Federal Circuit. The

majority (Judge Lourie joined by Judge Newman) did not even address this fundamental issue, much less identify any supporting authority or evidence for such an action. The fact is that the BPCIA contains no express mechanism for litigants to privately enforce the notice provision under Section 262(*l*)(8)(A). Nor can a private right of action be implied by the language or the structure of the Act. Indeed, the statutory text suggests just the opposite.

For one, the notice provision under Section 262(*l*)(8) "entirely lack[s] the sort of 'rights-creating' language critical to showing the requisite congressional intent to create new rights." *Gonzaga*, 536 U.S. at 287 (quoting *Alexander*, 532 U.S. at 288-89). Section 262(*l*)(8)(A) provides instructions to the aBLA applicant to provide advance notice of commercial marketing, while Section 262(*l*)(8)(B) provides that the RPS "may" seek a preliminary injunction where two preconditions to such an action have been met—(1) notice has been provided under subparagraph (A), and (2) the injunction is sought before the aBLA applicant has commercially marketed its biosimilar product. 42 U.S.C. § 262(*l*)(8)(A), (B). Separately, Section 262(*l*)(8)(C) simply provides that the parties will "reasonably cooperate" to expedite any discovery deemed necessary in any such injunction action. *Id.* at § 262(*l*)(8)(C). Nowhere in Section 262(*l*)(8) does the statute provide the RPS with a "right" to any notice, let alone a right to *enforce* the notice provision through an injunction proceeding.

Second, the BPCIA already contains remedies where the aBLA applicant elects not to provide notice of commercial marketing under Sec-

tion 262(*l*)(8)(A). As the Federal Circuit acknowledges, where the aBLA applicant has provided its application to the RPS but elects not to provide notice of commercial marketing under Section 262(*l*)(8)(A), an RPS may immediately bring a declaratory judgment action under Section 262(*l*)(9)(B) for patent infringement, validity or enforceability of any patent included in the initial list described in paragraph (3)(A), including as provided under paragraph (7). 42 U.S.C. § 262(*l*)(9)(B); App. 25a ("[P]aragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A) . . . ."); App. 51a n.2 (Chen, J. dissenting).

Alternatively, as Judge Chen observes in his dissent, where the aBLA applicant elects not to provide its application to the RPS, under Section 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C), an RPS, but not the aBLA applicant, may bring a declaratory judgment action for patent infringement, validity or enforceability of *any* patent that claims the biological product or use of the biological product. 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C); App. 51a (Chen, J. dissenting) ("Congress created the fallback provision of (*l*)(9)(C) for just these circumstances. An RPS does not need the remedy in (*l*)(9)(B) because (*l*)(9)(C) and § 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action when the (k) applicant fails to comply with (*l*)(2). At this point, the RPS possesses the statutory right to seek a preliminary injunction for any of its patents that 'could be identified pursuant to section [262](*l*)(3)(A)(i).'").

As this Court previously has acknowledged, "where a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. Nat'l Fed'n of Fed. Emps., Local 1263*, 489 U.S. 527, 533 (1989) (citing *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 19 (1979)). In such cases, absent strong evidence of contrary congressional intent, courts "are compelled to conclude that Congress provided precisely the remedies it considered appropriate." *Karahalios*, 489 U.S. at 533 (quoting *Middlesex Cty. Sewerage Auth. v. Sea Clammers*, 453 U.S. 1, 15 (1981)); *Alexander*, 532 U.S. at 290 ("The express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others."). This is true even where the statute may be interpreted as providing a benefit to those seeking to enforce it. *California v. Sierra Club*, 451 U.S. 287, 294 (1981) ("The question is not simply who would benefit from the Act, but whether Congress intended to confer federal rights upon those beneficiaries."); *Transamerica*, 444 U.S. at 24 ("[T]he mere fact that the statute was designed to protect advisers' clients does not require the implication of a private cause of action for damages on their behalf. The dispositive question remains whether Congress intended to create any such remedy." (citations omitted)). Indeed, "even where a statute is phrased in such explicit rights-creating terms, a plaintiff suing under an implied right of action still must show that the statute manifests an intent 'to create not just a private *right* but also a private *remedy*.'" *Gonzaga*, 536 U.S. at 284 (quoting *Alexander*, 532 U.S. at 286).

Here, Congress created the *sole* remedies for an alleged breach of Section 262(*l*)(8)(A) in Sections 262(*l*)(9)(B) and 262(*l*)(9)(C). There is no indication that Congress ever intended to provide any other remedies, including injunctive relief, for failure to provide effective notice of commercial marketing.

B. The Federal Circuit's Decision Does Not Comport With The Text Or Purpose Of The BPCIA.

The Federal Circuit's interpretation of Section 262(*l*)(8)(A)—requiring mandatory post-licensure notice—cannot be squared with the text or purpose of the BPCIA.

First, the stautory language contains no qualification on the pre-marketing notice save "[t]he subsection (k) applicant shall provide notice . . . not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). The plain language of the BPCIA thus supports Petitioner's argument that pre-marketing notice may come prior to licensure. To find otherwise, as Petitioner explains, the Federal Circuit dismissed one key word ("applicant") while reading another word ("licensed") out of its statutory context. *See* Pet. at 24-25; App. 18a-21a.

Second, by holding that Section 262(*l*)(8)(A) is a standalone provision requiring mandatory notice after licensure, the majority's interpretation provides, in dissenting Judge Chen's words, "an inherent right to an automatic 180-day injunction,"

which is at odds with the express language of the immediately succeeding section, Section 262(*l*)(8)(B). App. 52a (Chen, J., dissenting). Section 262(*l*)(8)(B) allows the RPS, "[a]fter receiving the notice," solely to "*seek* a preliminary injunction prohibiting the [aBLA] applicant from engaging in the commercial manufacture or sale of such biological product . . ." based on any patent(s) listed in the initial exchanges during the "patent dance" but not selected for litigation (*i.e.*, the so-called "phase-two patents"). 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). These statutory notice provisions may not be construed in isolation. *Samantar v. Yousuf*, 560 U.S. 305, 319 (2010). Congress did not create an automatic right to a 180-day injunction through Section 262(*l*)(8)(A); it granted, through Section 262(*l*)(8)(B), the more limited right for an RPS to "seek" such an injunction only, which the RPS may obtain solely by making the required showing on the merits and equities.

Third, the Federal Circuit's decision imposes an extra 180-day period of exclusivity, contrary to the structure and purpose of the BPCIA. As noted above, independent of any patent rights, Congress granted reference products four (4) years of exclusivity before an aBLA may be submitted and 12 years of exclusivity before an aBLA may be licensed. *See* 42 U.S.C. § 262(k)(7)(A), (B). These exclusivity provisions under Section (k)(7) (entitled "[e]xclusivity for reference product") are separate from the patent resolution procedures established in Section (*l*) (entitled "[p]atents")—the section which includes the notice of commercial marketing provision under Section § 262(*l*)(8)(A). Despite Congress's clear

intent to have such notice revolve around the resolution of patent disputes by including it in Section (*l*), the Federal Circuit erroneously converts the notice provision into an extra 180-day period of de facto exclusivity regardless of the RPS's patent rights.

The Federal Circuit's interpretation is at odds with the broader purpose of the BPCIA, too. As the court acknowledges, "[t]he BPCIA amended the Patent Act to create an artificial 'act of infringement' and to allow infringement suits based on a biosimilar application *prior to FDA approval* and prior to the marketing of the biological product." App. 6a. (emphasis added). Nevertheless, the Federal Circuit has created a mandatory 180-day *post*-licensure waiting period to purportedly provide the RPS with a "defined statutory window" during which the RPS may assert any remaining patent claims. App. 21a.

If Congress wanted biosimilar patent suits filed after licensure, there would have been no need to create an artificial act of infringement under Section 271(e)(2)(C). After licensure, a mechanism to resolve patent disputes already exists: the RPS may bring a declaratory judgment action and/or seek a preliminary injunction under other sections of the Patent Act such as 35 U.S.C. § 271(a) and/or (g). 35 U.S.C. § 271(a), (g); *see MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

But Congress specifically created a mechanism for early *pre*-licensure patent resolution through the BPCIA—a mechanism which RPSs and would-be biosimilar applicants alike endorsed. In fact, in

Congressional testimony presented during enactment of the BPCIA, a representative of the Biotechnology Industry Organization, which includes among its members RPSs like Amgen, testified that:

> Nearly all stakeholders in the biosimilar debates support inclusion of procedures to identify and resolve patent issues before a biosimilar is approved and placed on the market. . . . Providing a way to start patent litigation before the biosimilar product is on the market (*i.e.*, during the data exclusivity period of the innovator and while the biosimilar product cannot be marketed because it is undergoing review by the FDA) will benefit patients, physicians, insurers, follow-on manufacturers and innovators alike.

(Jeffrey P. Kushan, Prepared Statement On Behalf Of Biotechnology Indus. Org. on *Biologics and Biosimilars: Balancing Incentives for Innovation, Before the H.R. Subcomm. on Courts & Competition Policy, Comm. on the Judiciary*, 111th Cong. (July 14, 2009), http://judiciary.house.gov/_files/hearings/pdf/Kushan090714.pdf).

Interpreting the notice provision to delay litigation until after licensure frustrates Congress's goals of facilitating early patent resolution. Moreover, regardless of whether notice is given after licensure or at least 180 days before licensure, there still exists a "defined statutory window" within which any phase-two patent claims may be asserted.

The Federal Circuit defends its decision by explaining that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." App. 21a. According to the Federal Circuit, Congress meant for notice to follow licensure, so that "the product, its therapeutic uses, and its manufacturing processes are fixed." *Id.*

But this explanation contradicts the Federal Circuit's own statements, made just seven (7) months earlier in another BPCIA dispute involving the same parties and Amgen's patents covering its Enbrel® product. There, the Federal Circuit stated that the aBLA application itself "circumscribes and dominates the assessment of potential infringement." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014).

It is precisely this type of inherent contradiction that requires this Court's review. There is no statutory reason to hold an RPS's injunction efforts at bay until after licensure, given that Congress *created* the pathway by which an RPS may initiate suit—*pre*-licensure—after the parties engage in the patent dance (or immediately after an aBLA applicant reveals that it will not disclose its application or otherwise participate in the patent dance). In fact, following the Federal Circuit's reasoning to its logical extreme, if a crystalized controversy only exists after the biosimilar product, its therapeutic uses, and manufacturing processes are fixed by way of licensure, then all pre-licensure litigation is premature.

This view—which flows directly from the Federal Circuit's reasoning—is, of course, as illogical as it is absurd. No one disputes that a federal court has the jurisdiction to hear a case brought under the BPCIA and to issue appropriate injunction(s) if the RPS and the aBLA applicant engage in the patent dance and agree to immediately litigate patents identified pursuant to the patent exchange process—even if that litigation begins and ends years before licensure. *See generally* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6); 42 U.S.C. § 262(*l*)(4), (*l*)(6). Indeed, to date, Amgen has initiated five (5) different BPCIA actions, all filed prior to aBLA licensure, to assert various patent claims. *See Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741 (N.D. Cal. filed Oct. 24, 2014); *Amgen Inc. v. Apotex Inc.*, No. 15-cv-61631 (S.D. Fla. filed Aug. 6, 2015); *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839 (D. Del. filed Sept. 18, 2015); *Amgen Inc. v. Apotex Inc.*, No. 15-cv-62081 (S.D. Fla. filed Oct. 2, 2015); *Immunnex Corp. v. Sandoz, Inc.*, No. 16-cv-01118 (D.N.J. filed Feb. 26, 2016).

The same is true where the aBLA applicant refuses to disclose its application. In that instance, as the Federal Circuit recognizes, the RPS is entitled under Section 262(*l*)(9)(C) to file an immediate declaratory judgment action on "any patent that claims the biological product or a use of the biological product." 42 U.S.C. § 262(*l*)(9)(C). There is no indication that Congress believed the issues for purportedly relevant patents that were not initially selected for immediate litigation during the patent exchange process (*i.e.*, the so called "phase-two" patents) are any less "crystallized," and must be

resolved after licensure. Nor is there any indication that Congress intended for the parties to wait—possibly years—to conclude litigation over these phase-two patents, which only delays patent certainty for the aBLA applicant.

The Federal Circuit's interpretation proves even more illogical in situations where there are *no* relevant patents, all patents have *expired* by the time of licensure, or the parties have fully *resolved* their patent dispute before licensure. As noted above, this could happen with some frequency in the future, when the time between aBLA filing and licensure may extend eight (8) years or beyond. Nevertheless, under the Federal Circuit's decision, patient access will automatically be delayed by an additional 180 days post-licensure despite the lack of controversy over the RPS's patent rights.

This Court should grant review to ensure that the BPCIA's early patent resolution mechanism is allowed to work as intended.

C. The Federal Circuit's Creation Of An Automatic 180-Day Injunction Without Consideration Of The Equities Violates This Court's Precedent.

Review is required for the added reason that the Federal Circuit's decision to grant an automatic 180-day injunction in all circumstances, without any findings that satisfy the traditional requirements for equitable relief, runs afoul of this Court's precedent in *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006), which rejects any kind of "general rule" for an

automatic injunction under the Patent Act. 547 U.S. at 393-94. As this Court held, "a major departure from the long tradition of equity practice should not be lightly implied." *Id.* at 391 (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 320 (1982). This Court cautioned against "broad classifications" or "categorical rule[s]" when applying the traditional principles of equity and "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows" a statutory violation. *eBay*, 547 U.S. 392-93.

The Federal Circuit itself has recognized this Court's directive when it overruled its general practice of issuing permanent injunctions, without consideration of the traditional principles of equity, upon adjudication of infringement and validity under the Patent Act. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1148 (Fed. Cir. 2011); *see also SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 807 F.3d 1311, 1332 (Fed. Cir. 2015) ("Likewise, *eBay* clarifies that a patentee is not automatically entitled to an injunction—the patentee must prove that the equities favor an injunction." (citing *eBay*, 547 U.S. at 392)). Despite understanding and applying this Court's precedent in other circumstances, the majority effectively rewrites the notice provision as imposing an automatic injunction without any consideration of the equities.

There is no basis in the BPCIA, equity, or common sense to delay patient access to lower-cost biosimilars for even a day—much less 180 days—without a full consideration of the equities and justi-

fication on the merits of a patent claim. As discussed above, under the majority's interpretation, this automatic injunction would apply in all circumstances, independent of patent protection. This Court should, and indeed must, step in to ensure that its precedent is followed and injunctive relief is awarded only where the traditional requirements for equitable relief are met.

CONCLUSION

This case presents critical issues of first impression that can be addressed and corrected only by this Court. Absent review, the Federal Circuit's decision will inevitably deny patients lower-priced biologic medications, *in all cases*, longer than Congress intended, thus upsetting the careful balance of the BPCIA. The petition for certiorari should be granted.

Respectfully submitted,

MARCH 21, 2016

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RECORD AND BRIEFS

No. 15-1039

FILED
FEB 10 2017
OFFICE OF THE CLERK
SUPREME COURT, U.S.

In The

Supreme Court of the United States

SANDOZ INC., PETITIONER,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR PETITIONER SANDOZ INC.

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FEBRUARY 10, 2017

QUESTIONS PRESENTED

In the Biologics Price Competition and Innovation Act of 2009 ("Biosimilars Act" or "BPCIA"), Congress created an abbreviated regulatory pathway for the Food and Drug Administration ("FDA") to license "biosimilar" products—*i.e.*, products that are "highly similar" to approved biological products. 42 U.S.C. § 262(i)(2). The Biosimilars Act's "Notice of commercial marketing" provision states that a biosimilar applicant shall provide notice to the incumbent seller of the biological product "not later than 180 days *before the date of the first commercial marketing* of the biological product licensed under" this abbreviated pathway. *Id.* § 262(*l*)(8)(A) (emphasis added).

The Federal Circuit concluded that a biosimilar applicant "may only give effective notice of commercial marketing *after* the FDA has licensed its product." Pet. App. 20a (emphasis added). As the dissenting judge recognized, the Federal Circuit turned this mere notice provision into a grant of 180 days of additional exclusivity for all biological products beyond the exclusivity period Congress expressly provided—delaying the launch of all future biosimilars by six months. The Federal Circuit transformed the notice provision into a standalone requirement unconnected to the patent resolution provisions of the Biosimilars Act. It also disregarded the only remedy provided by Congress—the right to initiate patent litigation—and instead created its own extra-statutory injunctive remedy to bar the launch of FDA-approved biosimilars.

QUESTIONS PRESENTED—Continued

The questions presented are:

Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(*l*)(8)(A) as a standalone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper.

PARTIES TO THE PROCEEDING AND RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The parties to the proceeding are listed in the caption.[1]

Pursuant to Rule 29.6, petitioner Sandoz Inc. states the following:

Sandoz Inc. is an indirect subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

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[1] Amgen Inc. and Amgen Manufacturing Limited are both respondents. This brief refers to those entities collectively as "Amgen."

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The opinion of the court of appeals (Pet. App. 1a-55a) is reported at 794 F.3d 1347. The opinion of the district court (Pet. App. 56a-84a) is unreported but is available at 2015 WL 1264756.

JURISDICTION

The court of appeals entered judgment on July 21, 2015. Timely rehearing petitions were denied on October 16, 2015. Pet. App. 85a-86a. The Chief Justice extended the time for Sandoz to petition for a writ of certiorari to and including February 16, 2016, and Sandoz's petition was filed on that date. On March 21, 2016, Amgen filed a conditional cross-petition for a writ of certiorari. Both petitions were granted on January 13, 2017. This Court's jurisdiction rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The Biosimilars Act, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010), and the relevant provisions of Titles 28, 35, and 42 of the United States Code amended by the Biosimilars Act are reprinted in an appendix to this brief. App., *infra*, 1a-83a.

1. Section 262(*l*)(2)(A) of Title 42 provides:

> **(2) Subsection (k) application information**
>
> Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.

2. Section 262(*l*)(9)(C) of Title 42 provides:

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

3. Section 271(e) of Title 35 provides in part:

(2) It shall be an act of infringement to submit—

* * *

(C) * * *

(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act [42 U.S.C. § 262(*l*)(2)(A)], an

> application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act [42 U.S.C. § 262(*l*)(3)(A)(i)],

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

* * *

(4) * * *

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

4. Section 262(*l*)(8)(A) of Title 42 provides:

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

5. Section 262(*l*)(9)(B) of Title 42 provides:

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

INTRODUCTION

Congress enacted the Biologics Price Competition and Innovation Act of 2009 ("Biosimilars Act" or "BPCIA") to promote competition in the market for biologics, critical medicines made within cells or organisms. At the time, spending on biologics comprised one-fifth of pharmaceutical expenditures and was increasing. But there was no mechanism for approving "generic" forms of biologics, as there long had been for chemically synthesized drugs. Congress therefore created a shorter route for approval of "biosimilars," which are biologics highly similar to medicines already approved as safe and effective. In exchange, Congress gave 12 years of exclusivity from biosimilar competition to holders of licenses of those already-approved biologics ("sponsors" or "reference product sponsors")—regardless of whether the sponsor has any valid patent claims that otherwise could keep the biosimilar off the market.

Congress also established processes for early resolution of patent disputes between sponsors and applicants seeking to introduce biosimilars. At each step, Congress expressly spelled out what actions must be taken to continue, while providing multiple points at which the parties may exit, with specified consequences for doing so. Regardless of the choices the parties make along the way, all routes lead to only one place: patent litigation.

But the Federal Circuit turned one of the statute's procedural steps into an enforceable right unto itself.

Under that ruling, introduction of every single biosimilar will be delayed six months more than Congress intended. The Federal Circuit reached this result by misconstruing the statute's "Notice of commercial marketing" provision. That provision calls for the biosimilar applicant to give "notice to the reference product sponsor not later than 180 days *before the date of the first commercial marketing* of the biological product licensed under subsection (k)," that is, the abbreviated biosimilar pathway. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). This provision includes a single timing element: it is satisfied so long as notice is provided at least 180 days *before* commercial marketing. Nevertheless, the Federal Circuit interpreted it to include a second timing feature as well: the court thought notice could be given only *after* FDA approval of the biosimilar. Had Congress wanted that requirement, it would have said so directly, rather than by burying its intent in the single word "licensed," as the court of appeals concluded.

The Federal Circuit then compounded its error in two independent ways. The Biosimilars Act specifies consequences for not following its procedural steps. Yet the Federal Circuit erroneously added its own remedy: a mandatory, 180-day injunction against commercial marketing of the biosimilar, even *after* it is licensed by the FDA. In addition, rather than reading the statutory provisions in context and as part of a coherent design, the Federal Circuit erroneously read the notice provision as a freestanding requirement, divorced from

the role it plays in the statute's patent resolution regime.

The upshot of all these errors is a windfall for sponsors at the expense of competition and patients. The Federal Circuit held that notice may not be given until after FDA approval of a biosimilar, triggering a six-month waiting period for every biosimilar, enforceable by a mandatory injunction against commercial marketing. That means that sponsors receive 12 and one-half years of exclusivity from biosimilar competition, rather than the 12 years Congress intended. This will be true for every single biosimilar, even where the sponsor lacks any patent protection at all for its biologic or the parties already have resolved all their patent disputes.

The portion of the Federal Circuit's judgment on the notice of commercial marketing provision should be reversed, and the balance struck by Congress in the Biosimilars Act restored.

STATEMENT

A. Need For Biosimilar Approval Pathway

Biologics are medicines distinct from traditional, chemically synthesized pharmaceuticals (often referred to as "small-molecule" drugs). Biologics are either naturally occurring or engineered "from a variety of natural sources—human, animal, or microorganism." FDA, *What Are "Biologics" Questions and*

Answers (last updated Aug. 5, 2015) ("*What are 'Biologics'?*");[2] *see* 42 U.S.C. § 262(i)(1).

Biologics "often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available." *What Are "Biologics"?* Biologics are thus "among the most important pharmaceutical products available in the United States," but they also "generally are very expensive." Federal Trade Commission ("FTC"), *Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition*, 78 Fed. Reg. 68,840, 68,841 (Nov. 15, 2013).

When Congress passed the Biosimilars Act in 2010, purchases of biologics represented 21% of the $307 billion spent annually on medicines, and spending on biologics was increasing materially. CA JA A389-A391. Many individual biologics were extraordinarily costly. For example, the annual cost of Cerezyme, used to treat Gaucher's disease, was $200,000, and the annual cost of Humira, used to treat (among other things) Crohn's disease, was $51,000. Judith A. Johnson, Cong. Research Serv., RL34045, *FDA Regulation of Follow-On Biologics* 1 (2010) ("CRS Report").

At that time, there was no pathway for expedited approval for most "biosimilars," *i.e.*, biologics that are "highly similar" to already-approved biologics,

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[2] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm.

42 U.S.C. § 262(i)(2). By contrast, there had long been an abbreviated licensing process for generic small-molecule drugs under the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j). Competition from generic drugs made available through that process resulted in more than $1 trillion in savings to the U.S. healthcare system between 1999 and 2010. *See* Letter from John E. Dicken, Health Care Dir., Government Accountability Office ("GAO"), to Hon. Orrin G. Hatch, Ranking Member, Senate Comm. on Fin. 4, 10 (Jan. 31, 2012). The record before Congress showed that an abbreviated licensing process for biosimilars would create more competition and save government and private payors billions of dollars. CRS Report at 1, 4.

B. Statutory Background

To promote such competition and achieve those savings, Congress enacted the Biosimilars Act. Congress struck a careful balance in the statute between facilitating prompt access to cost-saving biosimilars and promoting innovation in biological products. Biosimilars Act § 7001(b), 124 Stat. at 804 (reproduced at App., *infra*, 45a).

The Biosimilars Act created an abbreviated pathway for approval of biosimilars. 42 U.S.C. § 262(k). To expedite market entry, the statute allows a biosimilar application to rely on the evidence of safety and efficacy for an already-approved reference product. *Ibid.*

In exchange, the Biosimilars Act gives holders of biologic licenses issued through the traditional approval pathway a lengthy period without any competition from biosimilars, regardless of whether sponsors have any valid patent claims. *Id.* § 262(k)(7).

The length of that exclusivity period was hotly contested during the consideration of the bill and its predecessors. The FTC argued that no exclusivity period was necessary. FTC, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* v, vii (June 2009) ("FTC Report").[3] By contrast, the biotechnology industry supported a 12-14 year exclusivity period. CRS Report at 3. The industry sought to justify that time period by arguing that patents did not adequately protect investment in biologics and this exclusivity period would substitute for patent protection. FTC Report at 25, 39-40. The President supported seven years. CRS Report at 3. As enacted, the Biosimilars Act provides that the FDA cannot "ma[k]e effective" approval of a biosimilar "until the date that is 12 years after the date on which the reference product was first licensed" by the FDA. 42 U.S.C. § 262(k)(7)(A).

To speed biologics to market once the 12-year exclusivity period expires, the Biosimilars Act also facilitates early resolution of potential patent disputes between sponsors and applicants. This process may begin when the biosimilar applicant files its

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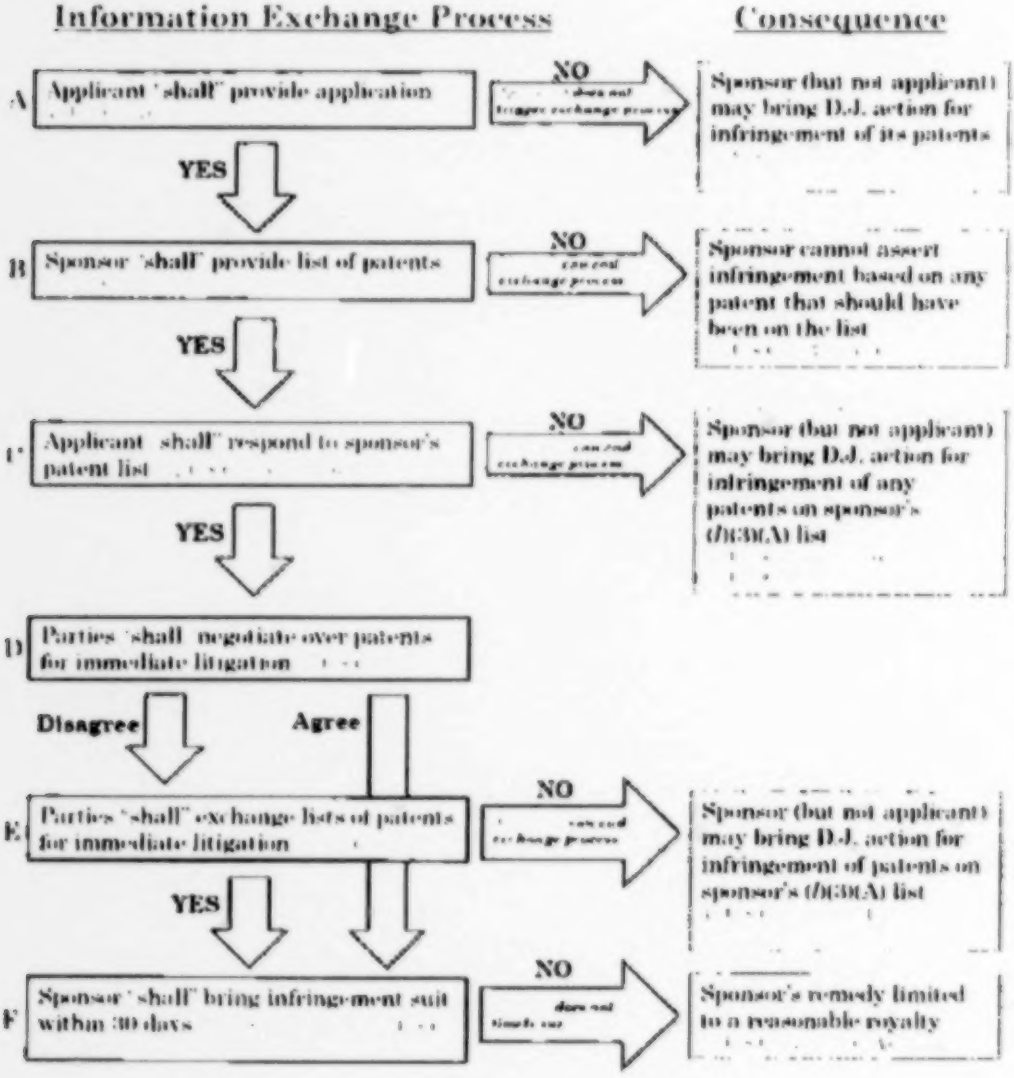
[3] https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competitionfederal-trade-commission-report/p083901biologicsreport.pdf.

application, which can happen as early as eight years before the sponsor's exclusivity period has expired. *See id.* § 262(k)(7)(B) (biosimilar applicant may submit its application to the FDA after the reference product has been licensed for at least four years). At that early time, a pre-marketing dispute over patent infringement and validity would not necessarily be of "sufficient immediacy and reality" to be litigated. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). To overcome that potential issue, the Biosimilars Act makes it an artificial "act of infringement to submit" a biosimilar application to the FDA under certain circumstances. 35 U.S.C. § 271(e)(2)(C); *cf. Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (discussing Congress's creation of an "artificial act of infringement" to "enable the judicial adjudication" of patent claims).

But the Biosimilars Act elsewhere limits who can obtain a declaratory judgment through those provisions, whether and when such actions can be brought, which patents can be included, and what other remedies are available—depending on the actions and inactions of the applicant, the sponsor, or both. 35 U.S.C. § 271(e)(2)(C), (4), (6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(*l*)(2)-(9). Regardless of the steps the parties do or do not take, however, the sole result is possible patent litigation. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (8)(B), (9)(A)-(C). Indeed, the statute specifies that patent-based remedies are "the *only* remedies which may be granted by a court" for the artificial

infringement created by the statute. 35 U.S.C. § 271(e)(4) (referring to *id.* § 271(e)(4)(A)-(D)) (emphasis added).

Such litigation can occur at various stages of the Biosimilars Act's patent dispute resolution regime (entitled "Patents"), 42 U.S.C. § 262(*l*). The various potential paths to patent litigation are illustrated in the following flowchart and explained in the text that follows:



Provision or non-provision of application ("A" in flowchart). As a condition precedent to starting the information exchange process, the applicant "shall provide to the reference product sponsor a copy of the [biosimilar] application" (and associated manufacturing information) within 20 days of the FDA's acceptance of the application. 42 U.S.C. § 262(*l*)(2)(A). The sponsor may use that information "for the sole and exclusive purpose of determining" whether it has a "reasonabl[e]" basis for a patent infringement claim. *Id.* § 262(*l*)(1)(D). If the applicant provides its application, neither it nor the sponsor may bring a declaratory judgment action on infringement, validity, or enforceability on certain patents until the applicant provides a notice of commercial marketing, *id.* § 262(*l*)(8)(A)-(B), or until another condition precedent is satisfied, *id.* § 262(*l*)(9)(B). *See id.* § 262(*l*)(9)(A).

If the applicant does *not* provide its application, the statute deems the submission of the biosimilar application to the FDA to be an artificial act of infringement. 35 U.S.C. § 271(e)(2)(C)(ii). And the sponsor may sue on any patents, including process patents. *Id.* § 271(e)(2); 42 U.S.C. § 262(*l*)(9)(C); Pet. App. 16a & n.3. In such litigation, the sponsor may obtain the biosimilar application in discovery. *See* Pet. App. 17a. By contrast, the applicant is barred from bringing a declaratory judgment action of non-infringement or invalidity for "any patent that claims the biological product or a use of the biological product." 42 U.S.C. § 262(*l*)(9)(C).

Provision or non-provision of patent list ("B" in flowchart). If the applicant provided its application, the sponsor has 60 days from receiving it to provide a list of patents for which it believes it could reasonably assert an infringement claim against the proposed biosimilar and to identify which patents it might license to the applicant. *Id.* § 262(*l*)(3)(A).

If the sponsor does not provide the list, it loses its ability to assert a patent infringement claim against the biosimilar based on any patent that should have been included on such list. 35 U.S.C. § 271(e)(6)(C).

Provision or non-provision of opinions ("C" in flowchart). If the sponsor provides a list, the applicant has 60 days to provide its non-infringement, invalidity, and unenforceability opinions on the sponsor's listed patents and also respond to the sponsor's identification of patents for a potential license. 42 U.S.C. § 262(*l*)(3)(B)(ii)-(iii). (The applicant may also provide its own list of the sponsor's patents for which the applicant "believes a claim of patent infringement could reasonably be asserted" by the sponsor. *Id.* § 262(*l*)(3)(B)(i).)

If the applicant does not provide its opinions, the sponsor (but not the applicant) may bring a declaratory judgment action for infringement of any patents on the sponsor's patent list. 35 U.S.C. § 271(e)(2)(C)(i); 42 U.S.C. § 262(*l*)(9)(B).

Narrowing of lists ("D" and "E" in flowchart). If the applicant provided its opinions, the sponsor "shall provide" within 60 days a "detailed statement"

providing "the factual and legal basis of the opinion of the reference product sponsor" that its identified patents "will be infringed" by the biosimilar and a "response to the [applicant's] statement[s] concerning validity and enforceability" of those patents. 42 U.S.C. § 262(*l*)(3)(C). The sponsor and applicant then "shall" negotiate in good faith over which patents should be litigated in an immediate suit. *Id.* § 262(*l*)(4)(A). If they "fail" to agree, they exchange lists of patents each believes should be litigated immediately. *Id.* § 262(*l*)(4)(B), (5). The "number of patents listed" by the sponsor cannot exceed the number listed by the applicant (unless the applicant lists no patents, in which case the sponsor may list only one). *Id.* § 262(*l*)(5)(B)(ii). The applicant thus can limit any immediate infringement suit to one patent.

If the applicant does not provide a list of patents in that exchange, the sponsor (but not the applicant) may bring a declaratory judgment action for any patents on the sponsor's original patent list. 35 U.S.C. § 271(e)(2)(C)(i); 42 U.S.C. § 262(*l*)(9)(B).

Litigation or not on listed patents ("F" in flowchart). If all prerequisite steps in the patent information exchange have been completed, the sponsor "shall bring" an infringement suit within 30 days on the patents agreed to by the parties or included in the exchanged lists. 42 U.S.C. § 262(*l*)(6)(A)-(B). (The Biosimilars Act also permits a second phase of litigation on any remaining or newly obtained patents. *See infra* p. 16.)

If the sponsor does not timely bring an infringement suit under subsection (*l*)(6) (or does so but dismisses it without prejudice or fails to prosecute it in good faith), "the sole and exclusive remedy" it may secure for any finding of infringement "shall be a reasonable royalty." 35 U.S.C. § 271(e)(6)(A)-(B).

Notice of commercial marketing. In addition, in subsection (*l*)(8)(A), the Biosimilars Act states that the applicant "shall provide notice" to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). When the parties have been engaging in the information exchange process, the notice of commercial marketing lifts the bar on declaratory judgment actions by either the applicant or the sponsor for listed patents (if any) that have not yet been litigated. *Id.* § 262(*l*)(9)(A). After receiving the notice, and before the date of "first commercial marketing" of the biosimilar, the sponsor may seek a preliminary injunction based on a showing of infringement of any not-yet-litigated patents. *Id.* § 262(*l*)(8)(B).

As with the above steps, however, the statute pairs the notice provision with an alternative procedural path. If the applicant does not provide the notice, the sponsor (but not the applicant) may bring a declaratory judgment action for any patents on the sponsor's original patent list (as well as any patents newly issued or licensed after the sponsor provided its original patent list). 35 U.S.C. § 271(e)(2)(C)(i); 42 U.S.C. § 262(*l*)(9)(B).

* * *

As this description shows, Congress linked steps in the information exchange process with consequences for not following them. Each consequence simply affects the scope and timing of patent litigation. For example, if the applicant does not take the first step (*i.e.*, provide its biosimilar application to the sponsor within 20 days of its acceptance by the FDA), *id.* § 262(*l*)(2)(A), the Biosimilars Act expressly lays out a specific path for resolving any patent disputes: patent infringement litigation, with the scope and timing at the sole discretion of the sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). In addition, where the applicant has initiated the information exchange process and the sponsor has provided its initial list of patents, the applicant's election not to provide the notice of commercial marketing means that "the reference product sponsor, but not the [biosimilar] applicant, may bring an action" for a declaration of infringement, validity, or enforceability of any patent on that list as well as any subsequently obtained patents. 42 U.S.C. § 262(*l*)(9)(B). Where the applicant has not triggered the information exchange process by providing its application, the sponsor already has a right to sue on any patent. *Id.* § 262(*l*)(9)(C).

In all cases—whether the information exchange process is never started, is started but not finished, or is followed to its end—the ultimate result is the same: patent litigation. *See* 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (8)(B), (9)(A)-(C).

C. Factual Background

1. Sandoz's biosimilar application

Since 1991, Amgen has marketed the biologic filgrastim under the brand name Neupogen®. Pet. App. 8a. Filgrastim is used to reduce the incidence of infection in certain cancer patients and to promote faster recovery in those who have undergone bone marrow transplants. Pet. App. 62a-63a.

On July 7, 2014, the FDA accepted for review Sandoz's application for biosimilar filgrastim. Pet. App. 8a. At that point, Amgen had already marketed its filgrastim biologic without biosimilar competition for twice as long as the 12 years Congress deemed sufficient to encourage innovation in biologics. *Ibid.*; 42 U.S.C. § 262(k)(7)(A). The day after the FDA accepted Sandoz's application, Sandoz notified Amgen that Sandoz had filed the application and that Sandoz expected FDA approval in the first half of 2015. Pet. App. 8a. Sandoz also provided notice that it intended to begin commercial marketing of its biosimilar filgrastim product in the United States immediately upon FDA approval. Pet. App. 8a; *see* 42 U.S.C. § 262(*l*)(8)(A) (notice of commercial marketing provision).

Amgen had publicly stated in filings with the Securities and Exchange Commission that it had no material, unexpired patents for filgrastim and that, as a result, it "now face[d] competition in the United States." CA JA A915, A960. Rather than engaging in the lengthy information exchange process to identify

patent claims Amgen had already said it did not have, Sandoz determined that lifting the bar on Amgen's ability to initiate immediate patent litigation was the best course. On July 25, 2014, Sandoz informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and that the Biosimilars Act thus permitted Amgen to bring a declaratory judgment action for patent infringement against Sandoz. CA JA A1495-A1497 (citing 42 U.S.C. § 262(*l*)(9)(C)).

2. Proceedings in district court

a. Several months later—in October 2014—Amgen sued Sandoz. Pet. App. 9a.

Amgen brought a claim under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, which provides a cause of action against "any unlawful, unfair or fraudulent business act or practice." Pet. App. 26a. Amgen alleged that Sandoz committed "unlawful" acts for purposes of the UCL by violating the Biosimilars Act. Pet. App. 9a. Specifically, Amgen alleged that Sandoz violated the Biosimilars Act (1) by not providing Amgen with Sandoz's biosimilar application within 20 days of FDA's acceptance of Sandoz's application and (2) by giving an allegedly premature, ineffective notice of commercial marketing before FDA approval. *Ibid.*[4]

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[4] Amgen also brought a state law claim for conversion, alleging that Sandoz wrongfully used Amgen's approved license for Neupogen®. Pet. App. 9a.

Expressly invoking the recourse provided by the Biosimilars Act, 35 U.S.C. § 271(e)(2)(C)(ii), Amgen also brought a claim for artificial infringement of Amgen's U.S. Patent No. 6,162,427, which claims a method of treating a patient using filgrastim. Pet. App. 9a; CA JA A79. But Amgen did not move for a preliminary injunction based on purported patent infringement (and still has not done so).

Sandoz counterclaimed, seeking declaratory judgments concerning, among other things, the correct interpretation of the Biosimilars Act. Pet. App. 9a.

b. On March 6, 2015, the FDA approved Sandoz's filgrastim product Zarxio®, the first biosimilar approved under the Biosimilars Act. Pet. App. 8a-9a. Although Sandoz "maintained that it gave an operative notice of commercial marketing in July 2014"—just after the FDA accepted its biosimilar application, *see supra* p. 18—Sandoz "nevertheless gave a 'further notice of commercial marketing' to Amgen on the date of FDA approval." Pet. App. 9a.

c. On March 19, 2015, the district court ruled for Sandoz on Amgen's state law claims and Sandoz's Biosimilars Act counterclaims. Pet. App. 56a-84a.

First, the district court concluded that it was lawful for Sandoz not to provide Amgen its biosimilar application within 20 days of acceptance by the FDA. Pet. App. 68a-73a. The court noted that Section 262(*l*)(2)(A) states that an applicant "shall provide" a copy of its application to the sponsor and that the information exchange provisions often "use the word 'shall' to

describe the parties' obligations under [subsection (*l*)'s] prescribed procedures." Pet. App. 69a. In context, however, the court explained that these provisions "demand that, if both parties wish to take advantage of [the Biosimilars Act's] disclosure procedures, then they 'shall' follow the prescribed procedures." *Ibid.* At the same time, the statute "contemplate[s] the scenario in which an applicant does not comply at all with disclosure procedures" by "allow[ing] the reference product sponsor to commence patent litigation immediately." Pet. App. 69a-70a.

Second, the district court concluded that it was lawful for Sandoz to provide its notice of commercial marketing before FDA approval, meaning that Sandoz's July 2014 notice was effective. Pet. App. 73a-76a. The court rejected Amgen's argument that the word "licensed" in the notice provision "means an applicant may not give the required 180-day notice to the reference product sponsor until *after* the FDA has granted approval of biosimilarity—resulting in a mandatory 180-day post-FDA approval waiting period prior to biosimilar market entry." Pet. App. 74a. The district court explained that "licensed" in the provision refers only to the fact that the product must be licensed before marketing and not to "the appropriate time for notice." Pet. App. 75a. The court further explained that "[e]ven more problematic with Amgen's reading" is that it would "tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A)." Pet. App. 75a-76a.

d. The district court entered final judgment under Federal Rule of Civil Procedure 54(b) on Amgen's state law claims and Sandoz's Biosimilars Act counterclaims. Pet. App. 11a.

3. Proceedings in the Federal Circuit

a. In May 2015, the Federal Circuit issued an injunction pending appeal, precluding Sandoz from marketing, selling, offering for sale, or importing into the United States its FDA-approved Zarxio® product. Pet. App. 31a; CAFC Dkt. No. 105.

b. On July 21, 2015, a fractured Federal Circuit panel affirmed the dismissal of Amgen's state law claims, vacated the judgment on Sandoz's counterclaims, and remanded. Pet. App. 1a-55a. The court also extended the injunction against commercial marketing of Sandoz's filgrastim through September 2, 2015—180 days from when the FDA approved the biosimilar and Sandoz provided its second notice of commercial marketing. Pet. App. 31a.

Disclosure of the application. A majority of the court of appeals panel (Judge Lourie joined by Judge Chen) agreed with Sandoz that the Biosimilars Act "explicitly contemplates" that an applicant might not take the first step in the information exchange process: disclosing its application to the sponsor under subsection (*l*)(2)(A). Pet. App. 15a. Accordingly, "the 'shall' provision in paragraph (*l*)(2)(A) cannot be read in isolation." *Ibid.* As the court explained, the Biosimilars Act "specifically sets forth the consequence" for not providing the application: "the [sponsor] may bring an

infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)," but the applicant remains barred from bringing its own declaratory judgment action. Pet. App. 15a-17a.

The court observed that the statute "has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A)." Pet. App. 15a-16a. Further, both provisions triggered by an applicant's failure to disclose its application "are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." Pet. App. 17a. "Because Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its [application] and the manufacturing information by the statutory deadline." Pet. App. 18a.

Judge Newman dissented from this part of the decision. Pet. App. 35a-42a (Newman, J., dissenting).

Notice of commercial marketing. The Federal Circuit interpreted the Biosimilars Act's notice of commercial marketing provision to mean that the "applicant may only give effective notice of commercial marketing *after* the FDA has licensed its product." Pet. App. 20a (emphasis added). The Federal Circuit read the phrase "licensed under subsection (k)" to require that notice "be given only after the product is licensed by the FDA," rather than as simply referring to the fact that the biosimilar will be licensed before marketing. *Ibid.* Based on this reading of the statute, the court

concluded that Sandoz's July 2014 notice of commercial marketing was "premature and ineffective" and that Sandoz's March 2015 notice "serves as the operative and effective notice of commercial marketing in this case." Pet. App. 23a.

Injunction. As noted above, a panel majority had concluded that the Biosimilars Act provides the exclusive consequence for not disclosing a biosimilar application under subsection (*l*)(2)(A). Pet. App. 15a. In contrast, however, a second majority (Judge Lourie joined by Judge Newman) did "not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with" the notice of commercial marketing provision in a case, like this one, where the information exchange process did not take place. Pet. App. 24a-25a. The majority acknowledged that subsection (*l*)(9)(B) expressly provides that if a biosimilar applicant does not provide its notice of commercial marketing, "'the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability'" of any patent included in the list prepared by the sponsor earlier in the information exchange process and any newly obtained patents. *Ibid.* (quoting 42 U.S.C. § 262(*l*)(9)(B)) (emphasis omitted).

The majority observed, however, that this consequence "does not apply" where, as here, the biosimilar applicant did not initiate the information exchange process because the referenced "list" of patents that could be the basis of a declaratory judgment action

does not exist. Pet. App. 25a. The majority further concluded that the notice provision is a "mandatory," "standalone" provision with which an applicant must comply, regardless of whether the applicant has disclosed its application under subsection (*l*)(2)(A) and initiated the information exchange process. Pet. App. 25a-26a.

The court then ruled (without specifying any source of its remedial authority to do so) that "Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015." Pet. App. 26a. And the majority fashioned its own injunctive remedy: "In light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended through September 2, 2015"—that is, 180 days from Sandoz's post-approval notice of commercial marketing. Pet. App. 31a.

Judge Chen dissented from this portion of the decision. Pet. App. 42a-55a. He criticized the majority's reading of the notice provision as giving the reference product sponsor "an extra-statutory exclusivity windfall." Pet. App. 44a. Judge Chen did not "view (*l*)(8)(A) as a 'standalone provision' that provides, implicitly, the [reference product sponsor] a 180-day injunction beyond the express twelve-year statutory exclusivity period." Pet. App. 43a-44a. He noted that Congress knew how to "create a 180-day automatic stay" if it wished to do so. Pet. App. 52a-53a. For example, Congress "could have tied FDA approval to the notice provision" by

providing that FDA approval cannot be effective until 180 days after notice is given. Pet. App. 53a.

Judge Chen explained that, "[w]hen reading (*l*)(8) in the context of subsection (*l*) as a whole, it becomes clear that (*l*)(8) is simply part and parcel of the integrated litigation management process contemplated in (*l*)(2)-(*l*)(7)." Pet. App. 43a. He would have held that, "when, as here, the [biosimilar] applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Ibid.* Moreover, recognizing that subsection (*l*) "concerns one thing: patent litigation," Pet. App. 45a, Judge Chen would have held that the Biosimilars Act provides the exclusive consequence for failure to provide 180 days' notice: the sponsor may sue for patent infringement. Pet. App. 51a-52a.

c. Sandoz launched its biosimilar filgrastim product Zarxio® in the United States on September 3, 2015—upon expiration of the Federal Circuit's injunction.[5]

SUMMARY OF ARGUMENT

The Federal Circuit erred by transforming a mere notice provision into a six-month bar on marketing FDA-approved biosimilars—enforceable by a judicially invented injunction and imposed even where no patent rights are at issue.

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[5] Despite the launch of Sandoz's biosimilar, the dispute between the parties remains live because it is capable of repetition yet evading review. *See* Pet. 36-37; U.S. Cert. Br. 22-24.

I. Under the plain text of Section 262(*l*)(8)(A), notice of commercial marketing can be given before FDA approval of a biosimilar. The provision includes one and only one timing constraint: the applicant is to give notice at least "180 days before the date of the first commercial marketing" of its biosimilar. There is no corresponding constraint stating that notice must come *after* FDA approval. And Congress knew how to require that an action be both "after" one event and "before" another—it used that express formulation in the provision immediately following subsection (*l*)(8)(A).

The Federal Circuit reached its contrary conclusion by overreading the word "licensed" in subsection (*l*)(8)(A). That word merely refers to the applicant's proposed biosimilar product, which will be "licensed" by the time of marketing. Nothing in the text provides that an applicant must wait until the FDA publicly approves its biosimilar, then provide "notice" of its self-evident intent to market that approved biosimilar, and then wait six months more before doing so. Had Congress intended such a scheme, it would have created it expressly instead of burying its intent in the word "licensed."

Permitting notice before approval advances subsection (*l*)(8)(A)'s purpose, which is to notify the sponsor that the biosimilar is at least 180 days from marketing and to lift any stay on any not-yet-litigated patents. That is consistent with the Biosimilars Act's focus on early resolution of patent disputes. Yet the

Federal Circuit's reading of the statute precludes certain litigation from even starting until after the FDA has approved a biosimilar.

II. Regardless of whether notice can be provided only after approval, the Federal Circuit independently erred by fashioning a private right of action for an extra-statutory injunction to enforce subsection (*l*)(8)(A). It is up to Congress, not the courts, to create private rights and remedies for their enforcement. The Biosimilars Act reflects no congressional intent to do so for the notice provision.

Congress created no private right in subsection (*l*)(8)(A). That provision plays only a procedural role by affecting the timing of certain patent infringement suits. Even if subsection (*l*)(8)(A) conferred a right, no extra-statutory remedy may be inferred for violating it. Congress already provided a remedy. Specifically, when an applicant engages in the information exchange process but does not provide notice of commercial marketing, "the reference product sponsor, but not the subsection (k) applicant, may bring" an action for a "declaration of infringement, validity, or enforceability" with respect to certain patents. 42 U.S.C. § 262(*l*)(9)(B). And when an applicant does not initiate the information exchange process, the sponsor already can file suit on all its patents. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Regardless, there is only one result: patent litigation.

These express remedies should have precluded the Federal Circuit from crafting additional ones. The unavailability of an injunction to enforce the notice provision is confirmed by the fact that Congress made a *different* provision of subsection (*l*) (involving confidentiality) enforceable by injunction. Effect must be given to Congress's choice to provide that remedy there but not here.

The Federal Circuit's ruling disrupts the careful balance struck by Congress. In exchange for provisions to speed competing biosimilars to market, Congress granted sponsors 12 years of exclusivity from competition from biosimilars, regardless of whether the sponsor has any valid patent claims. The Federal Circuit's ruling gives sponsors an additional 180-day injunction beyond that statutory period—thus effectively rewriting a central provision of the Biosimilars Act. And it does so even where the sponsor has *no* patent protection for its product.

III. Finally, the Federal Circuit erred by transforming subsection (*l*)(8)(A) into a standalone requirement unconnected to the Biosimilars Act's patent resolution provisions. The notice provision plays a procedural role in the information exchange process: it lifts the subsection (*l*)(9)(A) stay on litigation of certain not-yet-litigated patents. But where the applicant never triggered the information exchange process by providing its application, the stay as applied to the sponsor *already* has been lifted, authorizing the sponsor to start patent litigation on any and all patents.

Accordingly, in that circumstance, subsection (*l*)(8)(A) has no role to play and does not apply.

ARGUMENT

The Federal Circuit made three errors that result in effectively providing sponsors with six extra months of exclusivity beyond the 12 years Congress deemed sufficient. Its judgment on the notice of commercial marketing provision should be reversed.

I. NOTICE OF COMMERCIAL MARKETING MAY BE PROVIDED BEFORE FDA APPROVAL

The text, context, and purpose of the Biosimilars Act's notice of commercial marketing provision all establish that notice may be given before FDA approval of the biosimilar. The Federal Circuit's contrary reading—under which notice cannot come until after the FDA has already publicly approved the biosimilar—strips the "Notice of commercial marketing" provision of any notice function and instead converts it into a tool for delay for delay's sake.

A. The Text And Context Of Section 262(*l*)(8)(A) Demonstrate That Notice Can Be Provided Before FDA Approval

1. Titled "Notice of commercial marketing," Section 262(*l*)(8)(A) provides: "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A).

The provision includes one and only one timing limitation: at least "180 days *before* the date of the first commercial marketing" of the biosimilar. *Ibid.* (emphasis added). So long as that "180 days before" condition is satisfied, so too is Section 262(*l*)(8)(A). Nothing in the statutory text requires the applicant to wait until after FDA approval, then provide notice that it intends to market, and then wait six months more before bringing the biosimilar to market.

This plain-text reading of subsection (*l*)(8)(A) is confirmed by several other aspects of the statute.

First, an immediately neighboring provision demonstrates that Congress knew how to require that an action be both "after" one event and "before" another. Subsection (*l*)(8)(B) authorizes the sponsor to seek a preliminary injunction *"[a]fter* receiving the notice [of commercial marketing] under subparagraph (A) and *before* such date of the first commercial marketing * * * ." *Id.* § 262(*l*)(8)(B) (emphases added). Congress easily could have used the same structure in subsection (*l*)(8)(A) by requiring that notice be given "*after* receiving FDA approval and 180 days *before* the date of the first commercial marketing." It did not do so, and that choice should be given effect. *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("Had Congress intended to restrict § 1963(a)(1) to an interest in an enterprise, it presumably would have done so expressly as it did in the immediately following subsection (a)(2).").

Second, this interpretation is confirmed by Section 262(*l*)(8)(A)'s specification that it is the

"subsection (k) *applicant*" that provides the notice. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). The provision thus contemplates that the notifying party need only have requested FDA approval, not have received it. Elsewhere in the statute, Congress refers to parties with approved applications as "holders." *See id.* § 262(m)(3) (referring to "the holder of an approved application"). If Congress had meant to allow notice only after approval, it would have used consistent language here and called the notifying party "the holder of an approved application."

Third, the permissibility of pre-approval notice is confirmed by the provision's authorization of notice "*not later than* 180 days" before commercial marketing. *Id.* § 262(*l*)(8)(A) (emphasis added). Congress made 180 days the *minimum* notice period; nothing in the statute precludes applicants from giving earlier notice. Again, this reflects the Biosimilars Act's consistent goal of expedition and early resolution.

2. Despite all this support for the permissibility of pre-approval notice, the Federal Circuit thought its contrary rule lurked in the word "licensed" in the phrase, "the biological product licensed under subsection (k)." *Ibid.* ("The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of *the biological product licensed under subsection (k)*." (emphasis added)). According to the Federal Circuit, Congress's use of the word "licensed" "means that notice, to be effective under this statute,

must be given only after the product is licensed by the FDA." Pet. App. 20a.

This reading of the statute is wrong for multiple reasons.

Most fundamentally, the Federal Circuit's over-reading of the word "licensed" ignored this Court's admonition that Congress does not "hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001). The Federal Circuit's construction of "licensed" effectively extended the period of protection reference products enjoy from biosimilar competition from 12 years to 12 and one-half years. That is so because FDA licensure can come only after the reference product's 12-year exclusivity period. 42 U.S.C. § 262(k)(7)(A). If notice cannot be provided until after licensure—and if a 180-day waiting period can then be enforced by injunction, *see* Pet. App. 26a, 31a; *infra* Section II—then the exclusivity period would be extended by six months. As the district court observed, "[h]ad Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so." Pet. App. 76a.

Contrary to the Federal Circuit's view, the phrase, "the biological product licensed under subsection (k)," does no more than identify the product whose commercial marketing is relevant to measuring the 180-day period. Congress's use of "licensed" reflects the simple fact that, by the time the biosimilar is commercially marketed, it will be "licensed under subsection (k)." *See* 42 U.S.C. § 262(a)(1)(A); *see also* Pet. App. 75a

("'Before' modifies 'first commercial marketing'; 'licensed' refers only to 'biological product'—not the appropriate time for notice.").

This understanding is confirmed by another part of the Biosimilars Act, which provides the FDA with the "same" authority with respect to risk evaluation and mitigation strategies for "biological products *licensed under this subsection*" (*i.e.*, the biosimilar approval pathway) that the FDA has for "biological products licensed under subsection (a)" (*i.e.*, the traditional pathway). 42 U.S.C. § 262(k)(5)(C) (emphasis added). Despite the use of this "licensed under" phrasing, Congress expressly provided that the FDA could exercise this authority *before* approval. *See* 21 U.S.C. § 355-1(a)(1). Specifically, the FDA may require a company submitting an application under either subsection (a) or subsection (k)—"as part of such application"—to propose a strategy to ensure that the benefits of the proposed drug outweigh the risks. *Ibid.*; *cf. id.* § 355-1(a)(2) (separately authorizing FDA to require such a strategy after approval under certain circumstances if it becomes aware of new safety information). In other words, the phrase, "biological products licensed," in Section 262(k)(5)(C) imposes no temporal limitation on the provision's applicability. The FDA may require the applicant to develop mitigation strategies before approval, for use after the biologic is "licensed." Section 262(*l*)(8)(A) uses the phrase in the same way—notice may be given before approval of intent to commercially market a biosimilar once it is "licensed."

Section 262(k)(5)(C) also undermines the Federal Circuit's reliance on the word "licensed" in another respect. As just noted, the provision refers to both "biological products licensed under this subsection" (*i.e.*, the biosimilar approval pathway) and "biological products licensed under subsection (a)" (*i.e.*, the traditional pathway). 42 U.S.C. § 262(k)(5)(C). The Biosimilars Act uses these phrases and their equivalents to distinguish between the two different ways that a biologic product can be licensed. Elsewhere, for example, the statute provides that a biologic cannot be marketed unless "a biologics license under this subsection [*i.e.*, subsection (a)] or subsection (k) is in effect for the biological product." *Id.* § 262(a)(1)(A). The statute also defines a "reference product" as a "biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." *Id.* § 262(i)(4). The phrase, "the biological product licensed under subsection (k)," in subsection (*l*)(8)(A) is simply one way the statute refers to a biosimilar, as opposed to a biologic licensed under the traditional pathway.

B. Amgen's Textual Arguments Lack Merit

None of Amgen's additional textual arguments in support of the Federal Circuit's interpretation of Section 262(*l*)(8)(A) withstands scrutiny.

First, Amgen contends that if Congress had intended to permit pre-approval notice, subsection (*l*)(8)(A)

would have labeled the biosimilar " 'the biological product that is the subject of' the subsection (k) application"—a phrase used elsewhere in Section 262(*l*) —instead of "the biological product licensed under subsection (k)." Amgen Opp. 17; *accord* Pet. App. 20a. Unlike the provisions that use the "subject of" formulation, however, Section 262(*l*)(8)(A) is pegged to a specific point in time at which commercial marketing will take place and the biologic will therefore be "licensed." *See* Pet. App. 75a ("It would be nonsensical for subparagraph (*l*)(8)(A) to refer to a biosimilar as the subject of a subsection (k) application because upon its 'first commercial marketing' a biosimilar must, in all instances, be a 'licensed' product.").

Second, Amgen posits that the Biosimilars Act's interchangeability provisions support its view that notice cannot be provided until after FDA approval. *See* Amgen Opp. 18. Under those provisions, a second biosimilar cannot be certified as interchangeable until the earliest of five dates. 42 U.S.C. § 262(k)(6).[6] Amgen observes that one of those dates "is one year after the first commercial marketing of the interchangeable

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[6] The FDA will certify a biosimilar as "interchangeable" if it "can be expected to produce the same clinical result as the reference product in any given patient" and if "the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch." 42 U.S.C. § 262(k)(4). An interchangeable biosimilar "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product." *Id.* § 262(i)(3).

biosimilar, while another is eighteen months after the approval of that biosimilar." Amgen Opp. 18-19 (citing 42 U.S.C. § 262(k)(6)(A) and *id.* § 262(k)(6)(C)(ii)). Amgen then posits that comparison of these two triggering events "suggest[s] that first commercial marketing will not occur on the heels of FDA approval, but rather will follow that approval by some 180 days." *Ibid.*

These provisions have nothing to do with the notice of commercial marketing, and the obscure inference Amgen seeks to draw from them cannot overcome the lack of straightforward evidence for Amgen's post-approval timing requirement. As an initial matter, if Congress had meant to link these disparate concepts, it would have made the second triggering date "one year plus 180 days" after approval rather than "eighteen months" after approval—180 days is shorter than six months. Moreover, Section 262(k)(6) envisions that these end dates will be *different*: it calls for the end of interchangeability exclusivity on "the earlier of" a series of dates, including the two highlighted by Amgen. 42 U.S.C. § 262(k)(6). Yet Amgen's theory depends on the two periods being essentially the same. In any event, these provisions have nothing to do with commercial marketing of a biosimilar as a *biosimilar*. Rather, they apply when the first biosimilar meets the separate, more-demanding requirements of *interchangeability*. As the FDA has explained, approval of a biologic as interchangeable is a separate step that will typically take place subsequent to its approval as a biosimilar. *See* Draft Guidance, FDA, *Biosimilars:*

Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 6-7 (May 2015).[7] The time periods for calculating interchangeability exclusivity are thus beside the point.

Third, Amgen asserts that permitting notice before FDA approval renders Section 262(*l*)(9)(A) "meaningless." Amgen Opp. 19. That provision imposes a stay on litigation "[i]f a subsection (k) applicant provides" its biosimilar application to the sponsor, with the stay lifted when notice of commercial marketing is provided. 42 U.S.C. § 262(*l*)(9)(A). Amgen posits that "[i]f Sandoz were correct and an Applicant could give notice of commercial marketing as soon as it files its [application], the period in subparagraph 262(*l*)(9)(A) would end before it even began, rendering it meaningless." Amgen Opp. 19.

Amgen is wrong that the existence of this hypothetical would render Section 262(*l*)(9)(A) meaningless. In the specific fact pattern posited by Amgen, the applicant simply accelerates the parties' ability to move straight to litigation. *See* 42 U.S.C. § 262(*l*)(9)(A) (provision of notice lifts bar on declaratory judgment actions); *id.* § 262(*l*)(8)(B) (allowing sponsor to seek preliminary injunction on certain patents). The ability of a party in the information exchange process to choose one option over another does not render the forgone option superfluous. In any event, Amgen

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[7] http://www.fda.gov/downloads/Drugs/Guidances/UCM273001.pdf.

never explains why an applicant would behave so irrationally—providing its application to the sponsor (thus triggering the process meant to narrow and allow it to control the scope of immediate litigation) while simultaneously eliminating the value of that narrowing process by providing its notice of commercial marketing (thus inviting immediate litigation on any and all patents).

C. Permitting Notice Before FDA Approval Advances Section 262(*l*)(8)(A)'s Purpose

1. The purpose of Section 262(*l*)(8)(A) is manifest from its terms and express role in the statute: to provide the sponsor with "notice" that commercial marketing will commence in at least 180 days, *id.* § 262(*l*)(8)(A), so that, when the parties have been engaging in the information exchange process, the sponsor can seek a preliminary injunction based on any patents that have not yet been litigated, *id.* § 262(*l*)(8)(A)-(B), (9)(A). That purpose is advanced by permitting notice before FDA approval so that any remaining patent litigation can start—and litigation as to at least the merits of any patent-based preliminary injunction can finish—*before* expiration of the sponsor's 12-year exclusivity period.

In various ways, the Biosimilars Act promotes early resolution of patent disputes so that biosimilars can be available to patients as soon as the reference product's exclusivity ends. Congress made that purpose concrete by creating new artificial infringement

actions to allow patent suits before any actual infringement has occurred, long before FDA approval. *See* 35 U.S.C. § 271(e)(2)(C). Indeed, the mere filing of the biosimilar application allows the parties to start resolving patent disputes—through either the information exchange process followed by patent litigation, 42 U.S.C. § 262(*l*)(2)-(8), (9)(A)-(B); 35 U.S.C. § 271(e)(2)(C)(i), or immediate patent litigation, 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

Critically, it is the notice that triggers the sponsor's ability to seek a preliminary injunction on any patents that the sponsor has not yet been able to litigate through the information exchange process. *See* 42 U.S.C. § 262(*l*)(8)(B). Yet under the Federal Circuit's interpretation of the statute, that litigation cannot even *begin* until after FDA approval in *every* situation where the parties participate in the information exchange process. Nothing in the statute supports that result, which is entirely inconsistent with a statute structured to facilitate early resolution of patent disputes so that biosimilars can quickly reach patients. *See N.Y. State Dep't of Social Servs. v. Dublino*, 413 U.S. 405, 419-20 (1973) ("We cannot interpret federal statutes to negate their own stated purposes."). Moreover, the Federal Circuit's automatic six-month delay beyond FDA approval would apply even when there are *no* patents left to litigate—a particularly perverse outcome for a process that is all about patent rights. *See* Apotex Cert. Amicus Br. 13 (noting that in Amgen's litigation with Apotex *all* patents on the (*l*)(3) list were

litigated immediately after the information exchange, leaving nothing to be litigated under (*l*)(8)(B)).

2. The Federal Circuit's rule permitting "notice" only after FDA approval also deprives Section 262(*l*)(8)(A) of any *notice* function. There is no need for special notice after approval. FDA licensure of a biosimilar is a public act—the FDA itself provides public notice that a biosimilar may be commercially marketed. *See, e.g.*, Press Release, FDA, *FDA Approves First Biosimilar Product Zarxio* (Mar. 6, 2015) (announcing approval of Sandoz's application for filgrastim);[8] *see also* FDA, Center for Drug Evaluation and Research, List of Licensed Biological Products;[9] FDA, Drugs@FDA: FDA Approved Drug Products.[10]

The Federal Circuit thought that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." Pet. App. 21a. While the merits of that policy-based rationale can be debated, there is no basis for it in the text of the statute, which contemplates patent litigation well before (possibly *many years* before) FDA approval.

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[8] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.

[9] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm.

[10] http://www.accessdata.fda.gov/scripts/cder/daf/.

The Biosimilars Act's amendments to the patent laws establish a crystallized patent dispute upon the filing of a biosimilar application with the FDA and either non-provision of the application to the sponsor or the creation of a patent list. *See* 35 U.S.C. § 271(e)(2)(C); *see also Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014) (observing that in the artificial infringement actions created by the statute, it is the application that "circumscribes and dominates the assessment of potential infringement"). That can occur as early as *eight years* before the sponsor's exclusivity period expires. 42 U.S.C. § 262(k)(7)(A)-(B). And the first phase of patent litigation—which, at the applicant's option, can include *all* of the sponsor's asserted patents, 42 U.S.C. § 262(*l*)(5)(B)(i)(I), (ii)(II), & (6)(B)—commences no later than 250 days after the applicant is notified of acceptance of its biosimilar application. *See id.* § 262(*l*). If the applicant does not provide its application to the sponsor, the statute contemplates patent litigation on all the sponsor's patents even earlier. *See id.* § 262(*l*)(9)(C). All of these provisions permitting (indeed, encouraging) early resolution of patent claims cut against the Federal Circuit's interpretation of the notice provision to require the opposite result.

II. THE FEDERAL CIRCUIT ERRED BY INVENTING AN EXTRA-STATUTORY RIGHT OF ACTION AND INJUNCTION TO "ENFORCE" THE NOTICE OF COMMERCIAL MARKETING PROVISION

A. This Court's Precedents Foreclose Adding Judicially Created Remedies To Those In The Biosimilars Act

After concluding that the 180-day notice could not be given until after FDA approval, the Federal Circuit fashioned an injunctive remedy not specified in the Biosimilars Act and layered it on top of the remedies the statute does provide. In particular, the court of appeals created a private right of action for an automatic injunction to specifically enforce the notice of commercial marketing provision. Pet. App. 25a-26a, 31a; *see Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1060-61, 1063-65 (Fed. Cir.), *cert. denied*, 137 S. Ct. 591 (2016). This independent error provides a basis for reversal even if the Federal Circuit correctly decided that notice could not be provided until after FDA approval.

An injunction to enforce the Biosimilars Act's notice provision would be warranted only if supported by a showing of congressional intent to create "not just a private right" in that provision "but also a private remedy" for that right's violation. *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001); *see Gonzaga Univ. v. Doe*, 536 U.S. 273, 283-84 (2002) (private right of action can be implied only when "Congress intended to create a federal right" *and* intended "to create a private remedy"

for its enforcement (emphasis omitted)). Amgen can make neither showing.

1. The notice of commercial marketing provision creates no private right

The Biosimilars Act reflects no congressional intent to create any "private right" in Section 262(*l*)(8)(A). The notice of commercial marketing provision "lack[s] the sort of 'rights-creating' language critical to showing the requisite congressional intent to create new rights." *Gonzaga*, 536 U.S. at 287 (quoting *Sandoval*, 532 U.S. at 288-89). That is consistent with the purely procedural role the provision plays in the statute. Where the parties are engaged in the information exchange process, the notice authorizes the sponsor to file suit on listed patents not previously litigated. *See* 42 U.S.C. § 262(*l*)(8)(B), (9)(A). The only *substantive* rights involved are patent rights—and the only injunction contemplated by subsection (*l*)(8) is a "preliminary injunction" based on a showing of the strength of any such patents and the traditional requirements for injunctive relief. *Id.* § 262(*l*)(8)(B). Subsection (*l*)(8)(A) creates no substantive "right" to notice.

2. No injunctive remedy to enforce the notice provision is permissible

Even if Section 262(*l*)(8)(A) conferred a "right" on sponsors to receive a notice of commercial marketing (whether before or after licensure), no extra-statutory remedy for that right's "violation" may be inferred. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392

(2006) ("[T]he creation of a right is distinct from the provision of remedies for violations of that right."); *Sandoval*, 532 U.S. at 286. The remedy is provided by the Biosimilars Act itself. The Federal Circuit had no business adding its own remedy—a 180-day injunction against commercial marketing—to the one expressly provided by Congress.

"Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress." *Sandoval*, 532 U.S. at 286. Without a showing of congressional intent to create a private remedy, courts are not at liberty to fashion one. *Id.* at 286-87; *see Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 508 n.9 (1990) (limits on inferring rights of action "reflect[] a concern, grounded in separation of powers, that Congress rather than the courts controls the availability of remedies for violations of statutes"). Because "implied causes of action are disfavored," *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009), this Court is extremely reluctant to recognize them.

The demanding standard for implying a cause of action not expressly created by Congress is not satisfied here. Indeed, neither the Federal Circuit nor Amgen has cited *any* evidence of congressional intent to create a private injunctive remedy to enforce the notice provision—and there is none. Such a remedy is unavailable for that reason alone. But there is much more.

a. The statute's express remedies foreclose adding others

Where "a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. Nat'l Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989). "In such cases, '[i]n the absence of strong indicia of contrary congressional intent, we are compelled to conclude that Congress provided precisely the remedies it considered appropriate.'" *Ibid.* (quoting *Middlesex Cty. Sewerage Auth. v. Sea Clammers*, 453 U.S. 1, 15 (1981)).

Here, Congress specified that when an applicant engages in the information exchange process, yet does not provide notice of commercial marketing, "the reference product sponsor, but not the subsection (k) applicant, may bring" an action for a "declaration of infringement, validity, or enforceability" with respect to certain patents identified earlier in the information exchange process and any newly obtained patents. 42 U.S.C. § 262(*l*)(9)(B) (cross-referencing, *inter alia*, *id.* § 262(*l*)(8)(A)). And when an applicant has not initiated the information exchange process, its failure to provide the sponsor with its biosimilar application has *already* triggered the sponsor's ability to file suit on all its patents. *Id.* § 262(*l*)(9)(C).

These specified remedial consequences are consistent with Congress's approach throughout subsection (*l*). Instead of providing for judicial enforcement of the provision's steps through injunctions, the Biosimilars Act provides its own, patent-based remedies.

As Judge Chen correctly observed, "Entitled 'Patents,' § 262(*l*) of the BPCIA concerns one thing: patent litigation." Pet. App. 45a (Chen, J., dissenting). The actions or inactions of the applicant and sponsor under the Section 262(*l*) provisions all lead to only one result: a possible pre-approval patent infringement suit. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (9)(A)-(C). Moreover, the statute expressly provides that patent-based remedies "are the *only remedies* which may be granted by a court" for the artificial acts of infringement created by the Biosimilars Act. 35 U.S.C. § 271(e)(4) (emphasis added); *see ibid.* (exception only for attorneys' fees). With one significant exception discussed below, *see infra* Section II.A.2.b, the Biosimilars Act's express injunctive remedies all require a showing of possible infringement of a valid patent, as well as the traditional factors for an injunction. *Id.* § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(8)(B); *see eBay*, 547 U.S. at 394.

The statute's grant of these specific remedies should have precluded the Federal Circuit from crafting additional ones. *See Karahalios*, 489 U.S. at 533; *see also Great-W. Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 209 (2002) (noting that a statute's "carefully crafted and detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly" (internal quotation marks and citation omitted)).

Amgen contends that the Biosimilars Act's express remedies are insufficient and that enforcement

by injunction is therefore necessary to effectuate "Congressional purposes" behind the notice provision. Amgen Supp. Cert. Br. 9. Amgen's policy arguments are irrelevant. Absent congressional intent to create a remedy, that remedy "does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Sandoval*, 532 U.S. at 286-87. In any event, in a scheme that "concerns one thing: patent litigation," Pet. App. 45a (Chen, J., dissenting), offering patent-based remedies is fully sufficient to effectuate the statute's purposes.

Amgen raises the specter that an applicant without any securities-law disclosure obligations might "keep secret" its application, not provide notice, and somehow "surprise" the sponsor by commercially marketing the biosimilar. Amgen Supp. Cert. Br. 1. Again, Amgen's policy concerns with the remedies provided by Congress are immaterial. *See Sandoval*, 532 U.S. at 286-87. In any event, there is "no reason to believe that Congress feared" this unlikely scenario. *See Reynolds v. United States*, 132 S. Ct. 975, 984 (2012) (refusing to read statutory language "unnaturally" to avoid an "unrealistic possibility"). Indeed, Congress authorized a sponsor to file an infringement suit when the applicant does not provide its application, 35 U.S.C. § 271(e)(2)(C)(ii), reflecting its assumption that the sponsor would know about the filing of the application even when the applicant did not provide a copy. That understanding was correct. Filing a biosimilar application is a significant financial event—developing

a biosimilar requires eight to ten years and "between $100 and $200 million." FTC Report at 14.[11] All companies with approved biosimilars issued press releases upon filing their applications, including Amgen, which has its own biosimilars.[12] These companies also disclosed the application in their next securities filing.[13]

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[11] By contrast, it typically takes three to five years and costs $1 to $5 million to develop a generic version of a chemically synthesized drug. FTC Report at 14.

[12] Amgen, FDA Accepts Amgen's Biosimilar Biologics License Application For ABP 501 (Jan. 25, 2016), http://tinyurl.com/zkylhgu; Novartis, FDA accepts Sandoz regulatory submission for a proposed biosimilar etanercept (Oct. 2, 2015), http://tinyurl.com/plq5ebj; Celltrion, Celltrion files for US FDA approval of Remsima® (Aug. 11, 2014), http://tinyurl.com/gvbf9jz (approved under the name Inflectra®); Novartis, FDA accepts Sandoz application for biosimilar filgrastim (July 24, 2014), http://tinyurl.com/grl3p3o. Applicants with still pending applications have also issued press releases. *See, e.g.*, Apotex, Apotex Announces FDA Has Accepted For Filing its Biosimilar Application for Pegfilgrastim (Dec. 17, 2014), http://tinyurl.com/nvxywql; Amgen, Amgen And Allergan Submit Biosimilar Biologics License Application For ABP 215 To U.S. Food And Drug Administration (Nov. 15, 2016), http://tinyurl.com/junhlnz.

[13] Amgen, Form 10-K (Feb. 16, 2016) ("In January 2016, we announced that the FDA accepted for review our Biologics License Application (BLA) for ABP 501, a biosimilar candidate to Humira® (adalimumab)."), https://www.sec.gov/Archives/edgar/data/318154/000031815416000031/amgn-12312015x10k.htm; Novartis, Form 20-F (Jan. 27, 2016) ("The FDA and European Medicines Agency confirmed acceptance of our applications for etanercept, a proposed biosimilar to Amgen's Enbrel®, which treats autoimmune diseases such as rheumatoid arthritis and psoriasis."), https://www.sec.gov/Archives/edgar/data/1114448/000104746916009872/a2227040z20-f.htm; Celltrion, Form 10-K (Feb. 12, 2015) ("In August 2014, our partner Celltrion submitted an infliximab biosimilar application to the FDA for approval in the U.S."), https://

Furthermore, most applicants are conducting clinical trials to prove, among other things, biosimilarity. *See* 42 U.S.C. § 282(j); FDA, Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Guidance for Industry (Apr. 2015).[14] Certain of these trials must be publicly reported on a federal web site: clinicaltrials.gov. *See* Clinical Trials Registration and Results Information Submission, 81 Fed. Reg. 64,982, 64,982 (Sept. 21, 2016) (codified at 42 C.F.R. Part 111). Indeed, dozens of ongoing trials by biosimilar applicants and prospective applicants are now disclosed there.[15] Moreover, the FDA has held public advisory committee meetings before approval of biosimilars. *See, e.g.*, Oncologic Drugs Advisory Committee; Notice of Meeting, 79 Fed. Reg. 73,326, 73,326-27

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www.sec.gov/Archives/edgar/data/1274057/000127405715000012/hsp-201410xk.htm; Novartis, Form 20-F (Jan. 27, 2015) ("In the US, Sandoz completed Phase III trials, and the FDA accepted Sandoz's BLA for filgrastim, which was filed under the biosimilar pathway of the BLA."), https://www.sec.gov/Archives/edgar/data/1114448/000104746915000433/a2222787z20-f.htm.

[14] http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf.

[15] *E.g.*, A Study Comparing SB8 and Avastin® in Patients With Advanced Non-squamous Non-small Cell Lung Cancer (currently recruiting participants) (last verified Feb. 2017), https://clinicaltrials.gov/ct2/show/NCT02754882?term=bevacizumab+AND+biosimilar&recr=Open&rank=1; Immunogenicity and Pharmacodynamic of B12019 and Neulasta® in Healthy Subjects (currently recruiting participants) (last verified Sept. 2016), https://clinicaltrials.gov/ct2/show/NCT02912377?term=biosimilar&recr=Open&rank=8; Assessment of Pharmacokinetics (PK) and Safety of M834 and Orencia®, in Healthy Subjects (currently recruiting participants) (last verified Feb. 2017), https://clinicaltrials.gov/ct2/show/NCT02923583?term=biosimilar&recr=Open&rank=11.

(Dec. 10, 2014) (providing notice of advisory committee meeting in January 2015 to consider Sandoz's biosimilar filgrastim application, which was ultimately approved in March 2015); CA JA A1575-A1576 (news article about meeting).

Finally, even were it possible to "surprise" a sponsor by commercially marketing without notice, no rational applicant would do so in the face of potentially viable patents. This case proves that point: given the expense of entering the market and the harm of being removed by a patent injunction, Sandoz provided notice in an effort to litigate any potential patent claims before approval—even though Amgen had publicly announced it had no more patent coverage. Pet. App. 8a-9a; CA JA A915, A960.

b. Congress elsewhere provided for a mandatory injunction but not in subsection (l)(8)

Where Congress provides a particular type of remedy in one portion of a statute but not another, that choice must be given effect. *See Touche Ross & Co. v. Redington*, 442 U.S. 560, 571-72 (1979). In only one instance did Congress make a provision of Section 262(*l*) enforceable by injunction. When an applicant chooses to provide its biosimilar application to a sponsor, the Biosimilars Act extends certain confidentiality protections to the application. *See* 42 U.S.C. § 262(*l*)(1)(A)-(G). The statute expressly provides an injunctive remedy when these provisions are violated: "The disclosure of

any confidential information in violation of" the confidentiality rules "shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation." *Id.* § 262(*l*)(1)(H).

Nowhere else did Congress create a cause of action for either the applicant or the sponsor to obtain an injunction to compel the other party to comply with any of the provisions of Section 262(*l*). That absence is dispositive.

Section 262(*l*)(1)(H) highlights a second error in the Federal Circuit's analysis: the court enjoined Sandoz without regard to traditional equitable factors. This Court "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination" of a statutory violation. *eBay*, 547 U.S. at 392-93. The Court insists on clear evidence of congressional intent to depart from the "long tradition of equity practice" rejecting automatic injunctions. *Id.* at 395 (Roberts, C.J., concurring) (citation omitted). The text of the expressly mandatory injunction in Section 262(*l*)(1)(H) provides evidence of such intent. Congress provided no injunctive remedy at all to enforce the Biosimilars Act's other procedural provisions, much less a mandatory one like Section 262(*l*)(1)(H).

3. *The authority cited by the Federal Circuit in* Apotex *does not support creation of an extra-statutory injunction*

The Federal Circuit here offered no justification for the injunctive remedy it added to the Biosimilars Act. Although the court subsequently attempted to do so, its analysis is incorrect. *See Apotex*, 827 F.3d 1052.

The court in *Apotex* concluded that a 180-day injunction against commercial marketing is available because Section 262(*l*)(9)(B), which specifies the consequence for failing to comply with the notice provision, has no "text providing for exclusivity." *Id.* at 1064 ("There is no language that excludes other remedies for the conduct described.").

This approach—under which judicially fashioned remedies are allowed so long as not expressly foreclosed by Congress—is the opposite of the one mandated by this Court. In *Touche Ross*, this Court rejected the argument that where "Congress did not express an intent to deny a private cause of action [in a statute], this Court should infer one." 442 U.S. at 571. The Court held that "implying a private right of action on the basis of congressional silence is a hazardous enterprise." *Ibid.* Without evidence of Congress's affirmative intent to create the right of action in question, such an action is unavailable—whether or not Congress included a statement expressly foreclosing added remedies. *See ibid.*; *Sandoval*, 532 U.S. at 286.

The decisions the *Apotex* court cited lend no support to its inverse rule. *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946), does not stand for the proposition that courts are free to fashion injunctive remedies to enforce statutory provisions unless Congress specifically directs them not to do so. *Contra Apotex*, 827 F.3d at 1064. In that case, Congress expressly authorized the federal government to obtain an injunction against violations of a price-control statute and to obtain any "other order" in such proceeding. *Porter*, 328 U.S. at 397 (quoting Emergency Price Control Act of 1942, § 205(a), 56 Stat. 22, 33). The Court held that an order for restitution was an "other order" within this broad and express grant of equitable authority. *Id.* at 399. And because the statute was enforceable by the United States, the "public interest [was] involved," and the "equitable powers" of the district court "assume[d] an even broader and more flexible character than when only a private controversy is at stake." *Id.* at 398.

Mitchell v. Robert DeMario Jewelry, Inc., 361 U.S. 288 (1960), is similar. *See Apotex*, 827 F.3d at 1064 (citing *DeMario Jewelry*). In that case too, Congress had granted district courts broad equitable jurisdiction to permit the federal government to enforce the Fair Labor Standards Act. *DeMario Jewelry*, 361 U.S. at 289 (citing 29 U.S.C. § 217). The Court held that this express authority included not only the power to issue injunctions but also the power to order reimbursement for lost wages after an illegal discharge. *Id.* at 291-93. And, as in *Porter*, the Court relied on the principle that the courts' equitable powers are broader when invoked

by the government, as opposed to "when only a private controversy is at stake." *Id.* at 291 (quoting *Porter*, 328 U.S. at 398).

This case is fundamentally different. The Biosimilars Act confers no "comprehensive[] * * * equitable jurisdiction" to enforce its procedural provisions, *cf. Porter*, 328 U.S. at 398, nor has it "entrust[ed] to an equity court the enforcement" of the notice provision or the information exchange process, *cf. DeMario Jewelry*, 361 U.S. at 291. Moreover, disputes between sponsors and applicants under the statute are purely "private controvers[ies]" without the governmental enforcement element that this Court invoked in *Porter* to support the availability of broad remedial tools. *Cf. Porter*, 328 U.S. at 398; *DeMario Jewelry*, 361 U.S. at 291.

United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483 (2001), is even further afield. *Contra Apotex*, 827 F.3d at 1064. That decision addressed courts' ability to consider the public interest when deciding whether to grant an injunction. The Court explained that "when district courts are properly acting as courts of equity, they have discretion" to consider the public interest "unless a statute clearly provides otherwise." *Oakland Cannabis*, 532 U.S. at 496. Here, Congress did not direct district courts to "act[] as courts of equity" to enforce the Biosimilars Act's procedural provisions. *Cf. ibid.*

Finally, the *Apotex* court thought there was support for its position in the fact that subsection "(9)(B) does not make declaratory judgments exclusive and

thereby wipe out the remedies expressly provided for in 35 U.S.C. § 271(e)(4)." 827 F.3d at 1064-65 & n.4. The presence of expressly granted remedies does not support the Federal Circuit's analysis. Quite the opposite. The Biosimilars Act's express and interwoven remedies leave no room for courts to add their own. *See Karahalios*, 489 U.S. at 533.

B. By Delaying The Market Entry Of Every Biosimilar Product By Six Months, The Federal Circuit's Ruling Disrupts The Careful Balance Struck By Congress

The Federal Circuit's interpretation of the Biosimilars Act effectively rewrites key provisions and disrupts the careful balance struck by Congress. In enacting the statute, Congress sought to facilitate prompt access to cost-saving biosimilars while promoting innovation in biologics. Biosimilars Act § 7001(b), 124 Stat. at 804. To speed competing biosimilars to market, Congress allowed approval of biosimilar products to be based in part on previous approvals of reference products. Pet. App. 5a-6a; 42 U.S.C. § 262(i)(2), (k). In exchange, Congress granted sponsors up to 12 years of exclusivity from competition from biosimilars—regardless of whether the sponsor has any valid patent claims. 42 U.S.C. § 262(k)(7)(A).

Specifically, in a section titled "Exclusivity for reference product," Congress provided that the FDA's "[a]pproval of [a biosimilar] application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the

reference product was first licensed." *Ibid.* Under the clear terms of this provision, the FDA may issue an "effective" approval after the expressly granted exclusivity period has run. The biosimilar applicant should then be able to market immediately, absent the successful assertion by the sponsor of any valid patent claims.

Contrary to the statutory design, the Federal Circuit's ruling renders that "effective" approval *ineffective* for six months. The applicant must obtain FDA approval, then give notice (of the self-evident fact) that it intends to market that approved biosimilar, and then wait 180 days before marketing. Pet. App. 20a. Here, for example, the FDA licensed Sandoz's biosimilar on March 6, 2015, but the Federal Circuit blocked it from entering the market until September 3, 2015, based on no patent showing by Amgen. Pet. App. 8a-9a, 26a, 31a. As Judge Chen explained, this reading of the notice of commercial marketing provision gives the sponsor an "extra-statutory exclusivity windfall"—"a 180-day injunction beyond the express twelve-year statutory exclusivity period." Pet. App. 43a-44a (Chen, J., dissenting). The Federal Circuit's interpretation of the statute effectively gives all sponsors a six-month preliminary injunction after approval for every biosimilar—even if they have no patents covering the product—without meeting the high burden for obtaining such an injunction. But "[i]f Congress intended to create a 180-day automatic stay it understood how to do so." Pet. App. 52a-53a (Chen, J., dissenting). Indeed, Congress expressly extended the exclusivity period

to "12 years and 6 months rather than 12 years" for sponsors that successfully complete pediatric studies. 42 U.S.C. § 262(m)(2)(A).

Congress also "could have tied FDA approval to the notice provision" by providing that FDA approval cannot be effective until 180 days after notice is given. Pet. App. 53a (Chen, J., dissenting); *cf.* 21 U.S.C. § 355(j)(5)(B)(iii) (Hatch-Waxman Act's 30-month stay of effectiveness of FDA approval). Congress did not do so. Instead, it expressly directed that an approval after the expiration of the statutorily defined exclusivity period is "effective." 42 U.S.C. § 262(k)(7)(A).

The Federal Circuit attempted to downplay the significance of its holding by suggesting that the extra 180 days of exclusivity "will not likely be the usual case, as [applications] will often be filed during the 12-year exclusivity period for other products." Pet. App. 22a. That would not cure the problem created by its decision, even if there were a factual basis for that assertion. The Federal Circuit held that the "licensed product" language in subsection (*l*)(8)(A) means that notice cannot be given until the biosimilar is "licensed." Pet. App. 20a. But the biosimilar cannot be "licensed" until the 12 years of statutory exclusivity has run. *See* 42 U.S.C. § 262(k)(7)(A); Draft Guidance, FDA, *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* 2 (Aug. 2014) (explaining that the 12-year exclusivity period is "the period of time" during which the "FDA is not permitted to *license*" a

biosimilar (emphasis added)).[16] Thus, under the Federal Circuit's decision, an effective notice of commercial marketing cannot come until expiration of the 12-year exclusivity period. Pet. App. 20a. That would delay *all* biosimilars by 180 days.

For this same reason, the Federal Circuit's subsequent assertion in *Apotex* that the FDA could someday avoid providing sponsors with an extra six months of exclusivity fails. *See* 827 F.3d at 1062. According to the court of appeals, the FDA could in the future "issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date." *Ibid.* But the Federal Circuit held that notice may not be given until the biosimilar is "licensed." Pet. App. 20a. Once a product is licensed, it can be marketed. *See* 42 U.S.C. § 262(a)(1). Nothing the FDA does during the reference product's exclusivity period can "license" a biosimilar to be sold. *See* 42 U.S.C. § 262(k)(7)(A). Such an action therefore could not trigger the applicant's ability to provide notice under the Federal Circuit's reading of the provision.

Moreover, the FDA has no authority to issue a non-effective biologic "license." By contrast, the Hatch-Waxman Act expressly provides the FDA the power to grant tentative approval for generic small-molecule drugs. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd). That demonstrates that Congress acts expressly when it wishes to confer such authority to the FDA. It did not

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[16] http://www.fda.gov/downloads/drugs/guidancecompliance regulatoryinformation/guidances/ucm407844.pdf.

do so in the Biosimilars Act. In any event, the FDA does not consider a tentative approval under the Hatch-Waxman Act to be a license. *See* 21 C.F.R. § 314.107(b)(4) ("Tentative approval of a[] [new drug application ("NDA")] or [abbreviated new drug application ("ANDA")] does not constitute 'approval' of an NDA or ANDA and cannot, absent an approval letter from the Agency, result in an approval under paragraph (b)(3) of this section.").

That the Federal Circuit perceived the need to contort other statutory provisions in an attempt to soften the blow of its interpretation of the notice of commercial marketing provision "should have alerted" the court "that it had taken a wrong interpretive turn." *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2446 (2014). It is not permissible "to adopt unreasonable interpretations of statutory provisions and then edit other statutory provisions to mitigate the unreasonableness." *Ibid.* (internal citation, quotation marks, and ellipses omitted) (applying this principle to the EPA).

III. THE FEDERAL CIRCUIT ERRONEOUSLY DIVORCED THE NOTICE OF COMMERCIAL MARKETING PROVISION FROM THE PATENT RESOLUTION SCHEME

Even putting aside the questions of when notice may be given and whether courts may enforce the provision by automatic injunction, the Federal Circuit erred by transforming the notice provision into a standalone requirement unconnected to the Biosimilars Act's patent resolution provisions. *See FDA v.*

Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme."). As Judge Chen correctly concluded, the notice provision does not apply at all where, as here, the parties did not engage in the Biosimilars Act's information exchange process.

As outlined above, *see supra* pp. 12-16, the Biosimilars Act establishes an elaborate, multi-step process for resolving patent disputes—with options for patent litigation interwoven throughout. When a party declines to take one of the information exchange steps, the only result is an effect on the scope and timing of patent litigation. Indeed, the Biosimilars Act contemplated that the applicant might not initiate the process at all—giving the sponsor the unilateral right to initiate immediate patent litigation on the patents of its choosing. *See* 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii); Pet. App. 18a. When the parties' actions trigger that litigation-only path, the statutory context makes clear that the rest of the exchange process, including the notice provision, falls away.

In keeping with the rest of Section 262(*l*), the notice provision is "part and parcel to, and contingent upon, the preceding steps in the (*l*)(2)-(*l*)(8) litigation management regime." Pet. App. 50a (Chen, J., dissenting). In particular, the notice provision plays a role in the sequencing of litigation for parties that are engaging in, or that have completed, the information exchange process. As part of that process, declaratory judgment actions on certain patents are barred.

42 U.S.C. § 262(*l*)(9)(A). But when the applicant provides the notice of commercial marketing, the bar is lifted, and the sponsor may seek a preliminary injunction based on any patents that have not yet been litigated. *See id.* § 262(*l*)(8)(B), (9)(A). If the applicant declines to provide the notice, the stay is removed for the sponsor, but not the applicant. *See id.* § 262(*l*)(9)(B). "Thus, the entirety of (*l*)(8), including (*l*)(8)(A)'s notice provision, serves to ensure that [a sponsor] will be able to assert all relevant patents before the (k) applicant launches its biosimilar product." Pet. App. 48a (Chen, J., dissenting).

Both parts of Section 262(*l*)(8) therefore rest on the "express assumption that the parties have already performed the steps in (*l*)(3), and (*l*)(4)-(*l*)(5)." Pet. App. 49a (Chen, J., dissenting). "Without first engaging in these procedures, (*l*)(8) lacks meaning." *Ibid.* In particular, when the applicant did not trigger the information exchange process at all, providing the notice of commercial marketing cannot lift the stay on litigation of "remaining" patents. That is because the non-provision of the application *already* lifted the stay on litigation as to *all* patents, freeing the sponsor to file suit on any and all of them. *See* 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Under that scenario, there are not two separate phases of litigation over different sets of patents (with the applicant getting to limit the scope of the first phase). There is only one phase, whose timing and scope is entirely up to the sponsor.

The Federal Circuit observed that the statutory consequence specified for non-provision of the notice of commercial marketing "is a declaratory judgment action brought by the [sponsor] based on 'any patent included in'" the patent list it provided to the applicant. Pet. App. 25a; *see* 42 U.S.C. § 262(*l*)(9)(B). The court further observed that where, as here, the applicant did not trigger the information exchange process, no such list exists. Pet. App. 25a. The court perceived this supposed gap as a reason to allow for specific enforcement of the notice provision through an injunction. *Ibid.*

But this is a feature of the statute, not an inadvertent gap in its design. When the applicant does not trigger the information exchange process by providing its application, a sponsor "does not need the remedy in (*l*)(9)(B)" for failure to provide the notice "because (*l*)(9)(C) and [Section] 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action." Pet. App. 51a (Chen, J., dissenting). That Congress provided no separate consequence for failure to provide the notice in the non-information-exchange scenario simply shows that the notice provision is inapplicable.

CONCLUSION

The portion of the judgment involving the Biosimilars Act's notice of commercial marketing provision should be reversed.

Respectfully submitted,

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FEBRUARY 10, 2017

APPENDIX A

TITLE 28—JUDICIARY AND JUDICIAL PROCEDURE

PART VI—PARTICULAR PROCEEDINGS

CHAPTER 151—DECLARATORY JUDGMENTS

§ 2201. Creation of remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act.

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§ 2202. Further relief

Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.

APPENDIX B

TITLE 35—PATENTS

PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

CHAPTER 28—INFRINGEMENT OF PATENTS

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his

having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided

the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(*l*)(4) of the Public Health Service Act or the lists of patents described in section 351(*l*)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(*l*)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(*l*)(3)(A) of the Public Health Service Act, including as provided under section 351(*l*)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under

this section for infringement of the patent with respect to the biological product.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent,

no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

APPENDIX C

TITLE 42—THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A—PUBLIC HEALTH SERVICE

SUBCHAPTER II—GENERAL POWERS AND DUTIES

PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

SUBPART 1—BIOLOGICAL PRODUCTS

§ 262. Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c].

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c) of this section.

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(*o*), 505(p), and 505-1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(*o*), (p), 355-1].

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) Falsely labeling or marking package or container; altering label or mark

No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d) Recall of product presenting imminent hazard; violations

(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this paragraph, the term "base quarter", as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) Interference with officers

No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Penalties for offenses

Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Construction with other laws

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(h) Exportation of partially processed biological products

A partially processed biological product which—

(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) is not intended for sale in the United States; and

(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this chapter or the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

(i) "Biological product" defined

In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j) Application of Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including the requirements under sections 505(*o*), 505(p), and 505-1 of such Act [21 U.S.C. 355(*o*), (p), 355-1], applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed

for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) Additional information

An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available

information with respect to the reference product or another biological product.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) Evaluation by Secretary

Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) General rules

(A) One reference product per application

A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) Review

An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) Risk evaluation and mitigation strategies

The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) Exclusivity for first interchangeable biological product

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form,

delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) Guidance documents

(A) In general

The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(h)] with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) Public comment

(i) In general

The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) Input regarding most valuable guidance

The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) No requirement for application consideration

The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) Requirement for product class-specific guidance

If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) Certain product classes

(i) Guidance

The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) Modification or reversal

The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) No effect on ability to deny license

Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) In-house counsel

One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) Patent owner access

A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the

prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) Ownership of confidential information

The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the

use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a

claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of

which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes

should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product

sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before

the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product

sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph

(3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) Pediatric studies

(1) Application of certain provisions

The provisions of subsections (a), (d), (e), (f), (h), (i), (j), (k), (*l*), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(a), (d), (e), (f), (h), (i), (j), (k), (*l*), (n), (p)] shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(b), (c)].

(2) Market exclusivity for new biological products

If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to

the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a

timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(4) Exception

The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) [21 U.S.C. 355a(d)(3)] is made later than 9 months prior to the expiration of such period.

* * *

APPENDIX D

Public Law 111-148
111th Congress

An Act

Entitled The Patient Protection
and Affordable Care Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

* * *

TITLE VII—IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES

Subtitle A—Biologics Price Competition and Innovation

SEC. 7001. SHORT TITLE.

(a) IN GENERAL.—This subtitle may be cited as the "Biologics Price Competition and Innovation Act of 2009".

(b) SENSE OF THE SENATE.—It is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established.

SEC. 7002. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting "under this subsection or subsection (k)" after "biologics license"; and

(2) by adding at the end the following:

"(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

"(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

"(2) CONTENT.—

"(A) IN GENERAL.—

"(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

"(I) the biological product is biosimilar to a reference product based upon data derived from—

"(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

"(bb) animal studies (including the assessment of toxicity); and

"(cc) a clinical study or studies (including the assessment

of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

"(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

"(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

"(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

"(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that

the biological product continues to be safe, pure, and potent

"(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

"(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

"(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

"(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

"(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

"(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the

Secretary shall license the biological product under this subsection if—

"(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

"(i) is biosimilar to the reference product; or

"(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

"(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

"(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

"(A) the biological product—

"(i) is biosimilar to the reference product; and

"(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

"(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

"(5) GENERAL RULES.—

"(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

"(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

"(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

"(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on

the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

"(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

"(B) 18 months after—

"(i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

"(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

"(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

"(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection *(l)*(6).

For purposes of this paragraph, the term 'final court decision' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

"(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

"(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

"(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

"(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

"(i) a supplement for the biological product that is the reference product; or

"(ii) a subsequent application filed by the same sponsor or manufacturer of

the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

"(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

"(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

"(8) GUIDANCE DOCUMENTS.—

"(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

"(B) PUBLIC COMMENT.—

"(i) IN GENERAL.—The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

"(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish

a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

"(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

"(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

"(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

"(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

"(E) CERTAIN PRODUCT CLASSES.—

"(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

"(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

"(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

"(l) PATENTS.—

"(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION.—

"(A) APPLICATION OF PARAGRAPH.—Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the 'subsection (k) applicant') and the sponsor of the application for the reference product (referred to in this subsection as the 'reference product sponsor'), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

"(B) IN GENERAL.—

"(i) PROVISION OF CONFIDENTIAL INFORMATION.—When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause

(ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the 'confidential information').

"(ii) RECIPIENTS OF INFORMATION.—The persons described in this clause are the following:

"(I) OUTSIDE COUNSEL.—One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the 'outside counsel'), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

"(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

"(iii) PATENT OWNER ACCESS.—A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference

product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

"(C) LIMITATION ON DISCLOSURE.—No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

"(D) USE OF CONFIDENTIAL INFORMATION.—Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

"(E) OWNERSHIP OF CONFIDENTIAL INFORMATION.—The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

"(F) EFFECT OF INFRINGEMENT ACTION.—In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

"(G) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

"(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

"(H) EFFECT OF VIOLATION.—The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

"(2) SUBSECTION (K) APPLICATION INFORMATION.—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

"(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

"(B) may provide to the reference product sponsor additional information requested

by or on behalf of the reference product sponsor.

"(3) LIST AND DESCRIPTION OF PATENTS.—

"(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

"(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

"(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

"(B) LIST AND DESCRIPTION BY SUBSECTION (K) APPLICANT.—Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

"(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a

claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

"(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

"(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

"(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

"(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

"(C) DESCRIPTION BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

"(4) PATENT RESOLUTION NEGOTIATIONS.—

"(A) IN GENERAL.—After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

"(B) FAILURE TO REACH AGREEMENT.—If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference

product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

"(5) PATENT RESOLUTION IF NO AGREEMENT.—

"(A) NUMBER OF PATENTS.—The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

"(B) EXCHANGE OF PATENT LISTS.—

"(i) IN GENERAL.—On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

"(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

"(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

"(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR.—

"(I) IN GENERAL.—Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

"(II) EXCEPTION.—If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

"(6) IMMEDIATE PATENT INFRINGEMENT ACTION.—

"(A) ACTION IF AGREEMENT ON PATENT LIST.—If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

"(B) ACTION IF NO AGREEMENT ON PATENT LIST.—If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

"(C) NOTIFICATION AND PUBLICATION OF COMPLAINT.—

"(i) NOTIFICATION TO SECRETARY.—Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

"(ii) PUBLICATION BY SECRETARY.—The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

"(7) NEWLY ISSUED OR LICENSED PATENTS.—In the case of a patent that—

"(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

"(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

"(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION.—

"(A) NOTICE OF COMMERCIAL MARKETING.—The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

"(B) PRELIMINARY INJUNCTION.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

"(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by

the subsection (k) applicant under paragraph (3)(B); and

"(ii) not included, as applicable, on—

"(I) the list of patents described in paragraph (4); or

"(II) the lists of patents described in paragraph (5)(B).

"(C) REASONABLE COOPERATION.—If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

"(9) LIMITATION ON DECLARATORY JUDGMENT ACTION.—

"(A) SUBSECTION (K) APPLICATION PROVIDED.—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

"(B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (K) APPLICANT.—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

"(C) SUBSECTION (K) APPLICATION NOT PROVIDED.—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.".

(b) DEFINITIONS.—Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—

(1) by striking "In this section, the term 'biological product' means" and inserting the following: "In this section:

"(1) The term 'biological product' means";

(2) in paragraph (1), as so designated, by inserting "protein (except any chemically

synthesized polypeptide)," after "allergenic product,"; and

(3) by adding at the end the following:

"(2) The term 'biosimilar' or 'biosimilarity', in reference to a biological product that is the subject of an application under subsection (k), means—

"(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

"(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

"(3) The term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

"(4) The term 'reference product' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).".

(c) CONFORMING AMENDMENTS RELATING TO PATENTS.—

(1) PATENTS.—Section 271(e) of title 35, United States Code, is amended—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking "or" at the end;

(ii) in subparagraph (B), by adding "or" at the end; and

(iii) by inserting after subparagraph (B) the following:

"(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), an application seeking approval of a biological product, or

"(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act,"; and

(iv) in the matter following subparagraph (C) (as added by clause (iii)), by striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product";

(B) in paragraph (4)—

(i) in subparagraph (B), by—

(I) striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product"; and

(II) striking "and" at the end;

(ii) in subparagraph (C), by—

(I) striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product"; and

(II) striking the period and inserting ", and";

(iii) by inserting after subparagraph (C) the following:

"(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act."; and

(iv) in the matter following subparagraph (D) (as added by clause (iii)), by striking "and (C)" and inserting "(C), and (D)"; and

(C) by adding at the end the following:

"(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

"(i) that is identified, as applicable, in the list of patents described in section 351(*l*)(4) of the Public Health Service Act or the lists of patents described in section 351(*l*)(5)(B) of such Act with respect to a biological product; and

"(ii) for which an action for infringement of the patent with respect to the biological product—

"(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(*l*)(6) of such Act; or

"(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

"(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

"(C) The owner of a patent that should have been included in the list described in section 351(*l*)(3)(A) of the Public Health Service Act, including as provided under section 351(*l*)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.".

(2) CONFORMING AMENDMENT UNDER TITLE 28.—Section 2201(b) of title 28, United States Code, is amended by inserting before the period the following: ", or section 351 of the Public Health Service Act".

(d) CONFORMING AMENDMENTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) CONTENT AND REVIEW OF APPLICATIONS.—Section 505(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by inserting before the period at the end of the first sentence the following: "or, with respect to an applicant for approval of a biological product under section 351(k) of the Public Health Service Act, any necessary clinical study or studies".

(2) NEW ACTIVE INGREDIENT.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended by adding at the end the following:

"(n) NEW ACTIVE INGREDIENT.—

"(1) NON-INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is biosimilar to a reference product under section 351 of the Public Health Service Act, and that the Secretary has not determined to meet the standards described in subsection (k)(4) of such section for interchangeability with the reference product, shall be considered to have a new active ingredient under this section.

"(2) INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is interchangeable with a reference product under section 351 of the Public Health Service Act shall not be considered to have a new active ingredient under this section.".

(e) PRODUCTS PREVIOUSLY APPROVED UNDER SECTION 505.—

(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act; and

(B) such application—

(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle as the "Secretary") before the date of enactment of this Act; or

(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

(4) DEEMED APPROVED UNDER SECTION 351.—An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

(5) DEFINITIONS.—For purposes of this subsection, the term "biological product" has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(f) FOLLOW-ON BIOLOGICS USER FEES.—

(1) DEVELOPMENT OF USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) IN GENERAL.—Beginning not later than October 1, 2010, the Secretary shall develop recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of biosimilar biological product applications submitted under section 351(k) of the

Public Health Service Act (as added by this Act) for the first 5 fiscal years after fiscal year 2012. In developing such recommendations, the Secretary shall consult with—

(i) the Committee on Health, Education, Labor, and Pensions of the Senate;

(ii) the Committee on Energy and Commerce of the House of Representatives;

(iii) scientific and academic experts;

(iv) health care professionals;

(v) representatives of patient and consumer advocacy groups; and

(vi) the regulated industry.

(B) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(i) present the recommendations developed under subparagraph (A) to the Congressional committees specified in such subparagraph;

(ii) publish such recommendations in the Federal Register;

(iii) provide for a period of 30 days for the public to provide written comments on such recommendations;

(iv) hold a meeting at which the public may present its views on such recommendations; and

(v) after consideration of such public views and comments, revise such recommendations as necessary.

(C) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under subparagraph (B), a summary of the views and comments received under such subparagraph, and any changes made to the recommendations in response to such views and comments.

(2) ESTABLISHMENT OF USER FEE PROGRAM.—It is the sense of the Senate that, based on the recommendations transmitted to Congress by the Secretary pursuant to paragraph (1)(C), Congress should authorize a program, effective on October 1, 2012, for the collection of user fees relating to the submission of biosimilar biological product applications under section 351(k) of the Public Health Service Act (as added by this Act).

(3) TRANSITIONAL PROVISIONS FOR USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) APPLICATION OF THE PRESCRIPTION DRUG USER FEE PROVISIONS.—Section 735(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)(B)) is amended by striking "section 351" and inserting "subsection (a) or (k) of section 351".

(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—During the period beginning on the date of enactment of this Act and ending on October 1, 2010, the Secretary shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act (as added by this Act) during such period.

(C) AUDIT.—

(i) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs of reviewing such applications under such section 351(k). Such an audit shall compare—

(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

(II)(aa) such ratio determined under subclause (I); to

(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

(ii) ALTERATION OF USER FEE.—If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) to more appropriately account for the costs of reviewing such applications.

(iii) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability.

(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection such sums as may be necessary for each of fiscal years 2010 through 2012.

(g) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(m) PEDIATRIC STUDIES.—

"(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (i), (j), (k), (*l*), (p), and (q) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the

same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

"(2) MARKET EXCLUSIVITY FOR NEW BIOLOGICAL PRODUCTS.—If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

"(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

"(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

"(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS.—If the Secretary determines that information relating to the use of

a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

"(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

"(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

"(4) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) is made later than 9 months prior to the expiration of such period.".

(2) STUDIES REGARDING PEDIATRIC RESEARCH.—

(A) PROGRAM FOR PEDIATRIC STUDY OF DRUGS.—Subsection (a)(1) of section 409I of the Public Health Service Act (42 U.S.C.

284m) is amended by inserting ", biological products," after "including drugs".

(B) INSTITUTE OF MEDICINE STUDY.—Section 505A(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355b(p)) is amended by striking paragraphs (4) and (5) and inserting the following:

"(4) review and assess the number and importance of biological products for children that are being tested as a result of the amendments made by the Biologics Price Competition and Innovation Act of 2009 and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

"(5) review and assess the number, importance, and prioritization of any biological products that are not being tested for pediatric use; and

"(6) offer recommendations for ensuring pediatric testing of biological products, including consideration of any incentives, such as those provided under this section or section 351(m) of the Public Health Service Act.".

(h) ORPHAN PRODUCTS.—If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with,

such reference product may be licensed by the Secretary only after the expiration for such reference product of the later of—

(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

(2) the 12-year period described in subsection (k)(7) of such section 351.

SEC. 7003. SAVINGS.

(a) DETERMINATION.—The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle.

(b) USE.—Notwithstanding any other provision of this subtitle (or an amendment made by this subtitle), the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction.

* * *

RECORD AND BRIEF

FILED
MAR 31 2017
OFFICE OF THE CLERK
SUPREME COURT, U.S.

In The
Supreme Court of the United States

SANDOZ INC., PETITIONER,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED

AMGEN INC. AND AMGEN MANUFACTURING LIMITED, PETITIONERS,

v.

SANDOZ INC.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONSE AND REPLY BRIEF FOR SANDOZ INC.

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MARCH 31, 2017

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, petitioner/cross-respondent Sandoz Inc. states the following:

Sandoz Inc. is an indirect subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

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INTRODUCTION

Sandoz agrees with Amgen that the Biosimilars Act should be applied "as written." Br. 1. But that means applying the statute as written *in its entirety*—not just the parts Amgen rips from context and reads in isolation.

Congress enacted the Biosimilars Act to speed competing biologics to market while preserving incentives for innovation through a 12-year period of exclusivity from biosimilar competition. But to prevent patent litigation from delaying biosimilar cost savings at the end of that exclusivity period, Congress authorized early litigation between applicants and sponsors. In particular, it created new artificial acts of infringement, allowing patent suits potentially years before any actual infringement.

Congress then laid out different routes to pre-approval litigation. The statute outlines procedural steps and specifies litigation-related consequences depending on the parties' actions or inactions. For example, when the statute says that sponsors "shall" bring a patent suit within 30 days (42 U.S.C. § 262(*l*)(6)), it does not mean that a sponsor failing to do so violates the statute and can be compelled to sue. Rather, if a sponsor does not timely sue, its future patent remedies are limited. 35 U.S.C. § 271(e)(6)(A)-(B). In context, each step is not a freestanding command but a mandatory condition precedent to continuing the process.

Amgen addresses only half of this structure. It focuses exclusively on the procedural steps, disregarding the statute's express consequences for not following them. Amgen emphasizes the statute's mandatory language but fails to recognize the contingent nature of its commands: parties *must* take certain steps to start or continue the process, but if they do not, the statute explicitly sets out what happens as a consequence. In place of those consequences, Amgen asks the Court to invent new ones—causes of action for injunctions mandating procedural compliance. The statute "as written" precludes this approach.

The statute as written likewise forecloses Amgen's arguments about the notice of commercial marketing. The provision includes only one timing element—notice "not later than 180 days before" marketing. Yet Amgen seeks to inject a second timing element—no notice until after FDA approval. Had Congress wanted a "before" *and* an "after," it would have said so expressly (as in the very next provision).

Amgen's view is also contrary to the statute's purpose: patent litigation should be early and should not delay biosimilar competition. The notice allows litigation on any unlitigated patents, including newly issued ones. But under Amgen's view, such litigation could never even *begin* until after approval, making resolution impossible before a biosimilar product could be launched. And, perversely, a 180-day stay would apply even when no patents are left to litigate.

Amgen's interpretation extends the 12-year period of exclusivity from biosimilar competition to 12 years and 180 days. Congress focused intensely on the exclusivity period's length. It is inconceivable that Congress extended that period through the word "licensed" in the notice provision, rather than doing so expressly.

Amgen warns that rejecting its interpretations will cause "chaos" and rushed litigation. Amgen claims that an applicant would want to, and could, secretly develop and launch a biosimilar. Given applicants' need for patent certainty before launching products requiring investments of hundreds of millions of dollars and the ample public information about biosimilar development, Amgen's stealth launch scenario is fantasy. It obviously did not worry Congress—as shown by Congress's choice to authorize the sponsor to sue for patent infringement if the applicant does not provide its application or give notice. Congress's choice reflects its (correct) understanding that the sponsor would know when it could sue.

Similarly unpersuasive are Amgen's arguments about two rigid phases of litigation, new patents, and preliminary injunctions. Many of Amgen's hypothetical evils are also possible under its reading. And they ignore litigation realities that formed the backdrop against which Congress legislated. District courts and litigants are fully capable of handling those scenarios through complaint amendments, discovery, and other ordinary litigation tools.

It is Amgen's reading that promotes rushed litigation. Under Sandoz's view, an applicant could withhold its application, triggering immediate litigation on all patents without waiting 250 days to complete the information exchange process. That increases the odds that litigation would finish before FDA approval. And by allowing notice before approval (and, consistent with the statutory text, more than 180 days before marketing), Sandoz's reading would facilitate final judgment on any remaining patents before launch. Amgen's interpretation, by contrast, would squeeze all litigation on any remaining patents into a 180-day period, during which only a preliminary injunction, not a final judgment, could be obtained.

The Federal Circuit's judgment on the notice should be reversed and its judgment on provision of the application should be affirmed.

JURISDICTION

Sandoz incorporates its jurisdictional statement. Br. 1. The dispute remains live. Sandoz Br. 26 n.5; Pet. 36-37; U.S. Cert. Br. 22-24. Sandoz reasonably expects future biosimilars, including with Amgen as sponsor, where: if the subsection (*l*)(8)(A) judgment is reversed, Sandoz will provide pre-licensure notice, and if the subsection (*l*)(2) judgment is affirmed, Sandoz will withhold its application.

STATEMENT

Sandoz relies on its previous Statement (at 7-26).

REPLY IN NO. 15-1039

The Federal Circuit made three independent errors, resulting in 180 days' protection from biosimilar competition beyond the 12 years Congress provided.

I. NOTICE OF COMMERCIAL MARKETING MAY PRECEDE FDA APPROVAL

The text, context, and purpose of the notice of commercial marketing provision all show that notice may be given before FDA approval. Sandoz Br. 30-42; U.S. Br. 27-32.

A. The Text And Context Of Section 262(*l*)(8)(A) Demonstrate That Notice Can Precede FDA Approval

The notice of commercial marketing provision includes only one timing element: notice comes "180 days *before* the date of the first commercial marketing" of the biosimilar. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). The provision includes no "after" requirement, *i.e.*, no date after which notice must come.

The very next provision shows how Congress required an action to be both "after" one event and "before" another—*expressly*. Subsection (*l*)(8)(B) states that the sponsor may seek a preliminary injunction on unlitigated patents "[*a*]*fter* receiving the notice [of commercial marketing] under subparagraph (A) and *before* such date of the first commercial marketing." *Id.* § 262(*l*)(8)(B) (emphases added). This before/after structure "shows that Congress knew how to draft the kind of statutory language that [Amgen] seeks to read

into" subsection (*l*)(8)(A), but did not do so. *State Farm Fire & Cas. v. United States ex rel. Rigsby*, 137 S. Ct. 436, 444 (2016). This was the lead textual argument of Sandoz (at 31) and the United States (at 27). Amgen offers no response.

Sandoz explained (at 31-32) that its interpretation is confirmed by the specification that the "subsection (k) *applicant*" gives notice. This shows that the notifying party need only have requested, not received, approval. Amgen responds (at 29) that "[a]n applicant remains the 'person that submits an application under subsection (k)' even after the application is approved." Sandoz agrees. Notice can come before or after approval, and "subsection (k) applicant" describes the notifying entity either way. Under Amgen's view, however, Congress used "subsection (k) applicant" to refer *only* to entities holding granted applications. That would have been a bizarre choice. Adello Biologics Br. 13; *compare* 42 U.S.C. § 262(m)(3) (referring to "the holder of an approved application").

Amgen faults Sandoz for characterizing the provision's purpose as "inform[ing] the sponsor 'that commercial marketing will commence in *at least* 180 days.'" Amgen Br. 35 (quoting Sandoz Br. 39) (emphasis by Amgen). But that purpose is manifest from the text: it contemplates notice "*not later than* 180 days" before marketing. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). Sandoz made this textual point (at 32), yet Amgen offers no response.

Like the Federal Circuit, Amgen's entire textual argument rests on one word in subsection (*l*)(8)(A): "licensed." According to Amgen (at 28), this word refers "to products that have received FDA approval." Sandoz agrees. But showing what "licensed" means does not answer the question here: *when* does the relevant licensing take place? The provision measures its 180-day period backward from the future date of "*the first commercial marketing* of the biological product," at which point it will be "licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). Licensing occurs before the first commercial marketing, not before notice.

This use of "product licensed under" is not "unique." *Contra* Amgen Br. 23. As Sandoz explained (at 34), the Biosimilars Act uses this phrase in the risk-mitigation provision to refer to biosimilars both before and after approval. 42 U.S.C. § 262(k)(5)(C). Amgen does not disagree; instead it contends that this is due to 21 U.S.C. § 355-1(a)(1), which purportedly "extend[s]" risk-mitigation authority to pre-approval products. That is incorrect. Section 355-1(a)(1) did not "extend" anything; it existed *before* the Biosimilars Act. So when Congress used the phrase "products licensed under" in subsection (k)(5)(C), that reflected its background understanding that the phrase imposed no post-approval limitation. So too with subsection (*l*)(8)(A).

Sandoz also showed (at 35) that Section 262 uses "biological product licensed under subsection (a)," "biological product licensed under subsection (k)," and

equivalent phrases to distinguish the two ways biologics are licensed. Subsection (*l*)(8)(A) thus uses "biological product licensed under subsection (k)" to mean the biosimilar, as distinguished from the reference product. Amgen responds (at 29) that because "the provision already refers to '[t]he subsection (k) applicant[,]' * * * [n]o further clarification is necessary." Yet Amgen also argues that subsection (*l*)(8)(A)'s use of "'[t]he subsection (k) applicant' simply distinguishes the party that submitted the application from the reference product sponsor." *Ibid.* The same could just as easily be said of the phrase "biological product licensed under subsection (k)," which mirrors the opening phrase.

Amgen points (at 29) to other provisions "that refer to a product that will be licensed as the 'subject of the application' under subsection (k)." As Sandoz explained (at 36), none of those provisions measures a deadline from a specific future date when the biosimilar will be "licensed." *Accord* U.S. Br. 30. Moreover, using "subject of the application" in subsection (*l*)(8)(A) might have suggested notice could come *only* before approval. Instead, "180-day advance notice can occur either *before* licensing *or* * * * *after* licensing." *Id.* at 29-30.

B. None Of Amgen's Structural Arguments Establishes That Notice Must Await Licensure

Amgen erroneously contends (at 31) that "[t]he structure of §262(*l*) confirms that the marketing notice required by §262(*l*)(8)(A) must be provided after licensure."

Venue. Amgen asserts (at 32) that if an applicant provides its application under subsection (*l*)(2)(A) and simultaneously gives notice of commercial marketing, the applicant could sue immediately in the "venue of its choice." That is incorrect. That hypothetical applicant could not sue because the relevant artificial act of infringement requires a subsection (*l*)(3) list, which would not yet exist. 35 U.S.C. § 271(e)(2)(C)(i). The *sponsor* decides when to provide the subsection (*l*)(3) list and thus ripen the artificial infringement. If the applicant has given notice, the sponsor could simultaneously provide its list and seek a declaratory judgment in a venue of *its* choice. Regardless, that a lawsuit might be filed (by either party) in a proper venue says nothing about the statute's meaning.

Preliminary injunction. Because subsection (*l*)(8)(B) provides that a sponsor may seek a preliminary injunction on any unlitigated patents after receiving notice, Amgen contends the provision "indicates that the notice must come after licensure, when the need for such relief is presented." Br. 32-33. But notice also triggers the right to seek a declaratory judgment, 42 U.S.C. § 262(*l*)(9)(A), and, to the extent a preliminary injunction was also needed, Congress would have understood that its availability would turn on imminence and equitable considerations. *eBay v. MercExchange*, 547 U.S. 388, 392-93 (2006). Indeed, the statute includes no preliminary injunction provision for patents litigated in a subsection (*l*)(6) suit, instead implicitly relying on preexisting authority, *e.g.*, 35 U.S.C. § 283—which would be available only

if imminence and other requirements were satisfied. Similarly, just because subsection (*l*)(8)(B) states a sponsor may *seek* a patent-based preliminary injunction does not mean one will be warranted. And Amgen nowhere explains why such a provision should be read as sub silentio mandating a 180-day injunction without any showing of patent rights. Sandoz Br. 52; *contra* Amgen Br. 51 (speculating Federal Circuit considered equitable factors without mentioning them).

Process patents. Amgen contends that if the government is correct that "'[a]n artificial-infringement claim cannot rest on a manufacturing-process patent alone,'" then notice should await licensure because the sponsor could not assert artificial infringement of a process patent. Amgen Br. 33 (quoting U.S. Br. 25) (alteration by Amgen). But Congress's decision not to make process patents alone sufficient for artificial infringement, 35 U.S.C. § 271(e)(2), shows that Congress did not view them as needing pre-launch adjudication. Unlike a valid product or use patent, which might support an injunction to block launch (and would support an artificial infringement suit), a manufacturing process patent alone is unlikely to block launch because applicants will often be able to show that a different process could be used to make the product. Congress's choice to *deprioritize* litigation on process patents cannot support a reading that delays biosimilar marketing by 180 days to allow litigation on such patents.

New patents. Amgen observes that subsection (*l*)(7) provides for litigation of newly issued or licensed patents after notice. Br. 34. It then worries that

"early" notice could "completely disorder[]" such litigation with a "proliferation of patent suits filed as new patents issue or are licensed by the sponsor." *Ibid.* No textual evidence indicates Congress had any such concern, which ignores litigation basics. Sponsors with pending suits can assert newly acquired patents through amendment. Fed. R. Civ. P. 15. Amgen did just that here. Amgen Br. 57. Or they could file a new suit and consolidate it with the existing one. *Predator Int'l v. Gamo Outdoor USA*, 793 F.3d 1177, 1186-87 (10th Cir. 2015). There is nothing "disordered" about these ordinary litigation practices, which also would be used under Amgen's interpretation whenever new patents issue within 180 days after FDA approval. Moreover, delaying the start of litigation on all such patents until after approval would be contrary to the statute's purpose.

Interchangeability. Amgen points (at 34) to the five potential dates that end the first "interchangeable" biosimilar's exclusivity period. Noting that one date is one year after marketing and another is 18 months after approval, Amgen contends that "Congress expected a gap of roughly 180 days between licensure and marketing." But as Sandoz showed (at 37), Congress would not have chosen two dates that would be (under Amgen's theory) essentially the same, because it is the *earlier* of the five dates that ends the period. Amgen offers no response.

Sandoz also observed (*ibid.*) that six months is longer than 180 days. Had Congress meant to link the notice of commercial marketing and interchangeability

provisions, it would have made the second date "one year plus 180 days" or explicitly referred to the end of the notice period. *Ibid.* Amgen waves this off by positing (at 35) that "Congress gave the applicant a few days' grace period before terminating the incentive for achieving the first interchangeable product." Amgen cites nothing for this "grace period" theory.

Regardless, the interchangeability provisions are immaterial. Amgen asserts (at 35) that because "interchangeable products are a subset of biosimilars," subsection (*l*)(8)(A) should not "appl[y] differently to interchangeable biosimilars than to biosimilars in general." But subsection (*l*)(8)(A) does not apply *at all* to the first marketing of a biosimilar *as an interchangeable*, which typically comes *after* its first marketing as a biosimilar. Sandoz Br. 37-38.

C. Permitting Notice Before FDA Approval Advances Section 262(*l*)(8)(A)'s Purpose

Sandoz explained (at 39-42) that permitting notice before approval advances the statute's purpose of facilitating early resolution of patent disputes. The Federal Circuit's ruling makes the parties wait—potentially for years—before even *starting* litigation on any previously unlitigated patents.

1. Amgen's arguments based on two rigid litigation "phases" are meritless

Amgen agrees that Congress intended early resolution of patent disputes. It contends, however, that this goal was limited to so-called "Phase One" litigation

and that Congress wanted so-called "Phase Two" to happen as late as possible—after the biosimilar's approval. Br. 36-40. Amgen then contends (at 31) that if applicants could provide notice "at any time," then "phase-two litigation" under subsections (*l*)(9)(A) and (*l*)(8)(B) might "subsume" subsection (*l*)(6) "phase-one litigation." Amgen's vision of two rigidly bifurcated "phases" is meritless.

First, overlap between the "phases" would also happen under Amgen's interpretation. Amgen acknowledges (at 38) that "phase-one litigation" may not be concluded by approval. When that happens, even under Amgen's theory, the statute permits applicants to provide notice and trigger "phase two" litigation before "phase one" has ended.

Second, the statute contemplates the possibility of only one "phase" of litigation, where the sponsor does not secure new patents after the information exchange process. It gives the applicant unilateral control over the scope of the subsection (*l*)(6) suit, and the applicant could choose to litigate immediately every patent on the subsection (*l*)(3) lists. Sandoz Br. 42. This demonstrates Congress was not concerned about patent litigation happening too early.

Citing nothing, Amgen suggests (at 15) that subsection (*l*)(5)'s mechanisms for selecting patents to litigate immediately "require the parties to identify patent claims that can meaningfully be adjudicated or otherwise resolved before the FDA determines what, precisely, will be licensed." The statute contains no

such "require[ment]." Rather, it authorizes the applicant to choose the patents for the subsection (*l*)(6) lawsuit. 42 U.S.C. § 262(*l*)(5). Indeed, if the Court considers witness statements from earlier Congresses (the main source of Amgen's "legislative history," *infra* pp. 29-30), one witness explained that the applicant should have this control because it could best determine which patents might block entry and thus require immediate litigation. Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 736 (2010). An applicant that has spent years and hundreds of millions of dollars developing a biosimilar has every incentive to attain patent certainty as early as possible. *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 119 (2007) (statement of Bruce L. Downey, Chairman of the Board, Generic Pharmaceutical Association).

In sum, where the parties engage in the information exchange, the main event is the subsection (*l*)(6) suit, not any mop-up suit that might follow notice.

Third, providing notice merely allows litigation to commence on any not-yet-litigated patents. 42 U.S.C. § 262(*l*)(9)(A). If that occurred during the subsection (*l*)(6) suit's pendency, no "chaos" would ensue. New patents could simply be added to the existing suit (or a new suit coordinated with the existing one). In many cases, there may be *no* such patents.

Apotex Br. 19 (all patents in Apotex-Amgen case were litigated in subsection (*l*)(6) suit).

Finally, contrary to Amgen's hypothesis (at 39), an applicant engaging in the information exchange years before the exclusivity period expires (unlike here) would have no incentive to give notice so early. The information exchange process gives the applicant considerable control, as Amgen's amici acknowledge. Biotechnology Innovation Organization ("BIO") Br. 23. But notice eliminates that control by allowing the sponsor to sue on all patents. A rational applicant would therefore not give notice until nearer approval. Coherus Br. 17-18.

2. *Sandoz's interpretation, not Amgen's, promotes "patent certainty" and minimizes rushed litigation*

Amgen posits (at 47) that subsection (*l*)(9)(A) lifts the bar on declaratory judgment actions on non-litigated patents to "ensure[] that the applicant can obtain patent certainty before launch." But it is Sandoz's reading—not Amgen's—that increases the chance of pre-launch certainty.

Under Sandoz's reading, if exclusivity has not run, notice can be provided early enough to allow for final declaratory judgments on infringement or invalidity on all patents *during the exclusivity period*—thus providing true patent certainty. Under Amgen's interpretation, however, litigation on any patents not adjudicated under subsection (*l*)(6) cannot even *start* until after approval, which is necessarily after exclusivity

expires. Amgen would compress that litigation into 180 days, almost never enough time to secure final judgment in district court, much less to exhaust appeals. Thus, Amgen's interpretation, not Sandoz's, will lead to rushed litigation. *Contra* Amgen Br. 40-41.

This is true despite Amgen's emphasis (at 39) on the immediacy requirement for injunctive relief. Amgen posits that if an applicant gave notice "long before" licensure, the sponsor would not know when harm would be sufficiently immediate for a preliminary injunction. *Ibid.* But in those circumstances, a preliminary remedy would likely be unnecessary because there would be time for final declaratory judgments. If the sponsor prevailed, the applicant would not launch—even absent an injunction—because marketing a product after final declaratory judgment of patent infringement would almost certainly subject the applicant to treble damages, attorneys' fees, and an immediate injunction. 35 U.S.C. § 284; 28 U.S.C. § 2202; *Halo Elecs. v. Pulse Elecs.*, 136 S. Ct. 1923, 1931-33 (2016); *see Samuels v. Mackell*, 401 U.S. 66, 72 (1971) ("[E]ven if the declaratory judgment is not used as a basis for actually issuing an injunction, the declaratory relief alone has virtually the same practical impact as a formal injunction would.").

Moreover, Amgen's concern that a sponsor would have no idea when launch was imminent (and thus when to seek a preliminary injunction) disregards how patent litigation works. Sponsors undoubtedly will propound discovery about the timing of approval and launch. *See* Fed. R. Civ. P. 26, 33. And applicants will

have an ongoing duty to update that information. Fed. R. Civ. P. 26(e)(1). Sponsors would also have access to ample public sources about biosimilars' development. Sandoz Br. 48-51; Biosimilars Council Br. 28-30, 34-35.[1]

Finally, Amgen's discussion (at 36-37) of the possibility of amendments to a biosimilar application provides no support for prohibiting pre-approval notice. Essentially all information submitted while FDA reviews an application is lodged as an "amendment." *See* Center for Biologics Evaluation & Research SOPP 8402, IV.A;[2] SOPP 8001.4, V.L.[3] Indeed, Amgen cites an amendment that merely changed the name of

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[1] Amgen's concern that "[e]ven a speedily issued preliminary injunction or temporary restraining order may not be quick enough to prevent large-scale market incursion by an infringing product" (Br. 41) is misplaced for biosimilars. Unlike small-molecule generics, pharmacies cannot unilaterally switch patients to (non-interchangeable) biosimilars; a prescription for the biosimilar itself is required. FDA, Information for Healthcare Professionals (Biosimilars), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241719.htm (last updated Jan. 12, 2017). Biosimilars thus have much slower market penetration than small-molecule generics. *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 111th Cong. 32, 78-79 (2009) (statement of Federal Trade Commissioner Pamela Jones Harbour and FTC Report on Follow-On Biologic Competition).

[2] https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073461.htm.

[3] https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm063086.htm.

Sandoz's proposed product. Center for Drug Evaluation and Research, Proprietary Name Review(s) (July 23, 2014).[4]

In any event, the sponsor can simply "propound discovery requests under Federal Rules of Civil Procedure 33 and 34 to monitor amendments to the biosimilar application, and, should such an amendment impact the infringement analysis, it can add or remove patents from the case as appropriate." Coherus Br. 16-17. Amgen dismisses this as a "'shoot first, ask questions later' approach" (at 37 n.4), but it is "routinely done in cases involving generic drugs under the Hatch-Waxman Act." Coherus Br. 17. Here, Amgen received all of Sandoz's amendments in discovery yet saw no need to amend its complaint.

II. THE FEDERAL CIRCUIT ERRED BY INVENTING AN EXTRA-STATUTORY RIGHT OF ACTION AND INJUNCTION TO "ENFORCE" THE NOTICE PROVISION

After erroneously concluding that notice must come after FDA approval, the Federal Circuit invented a judge-made cause of action and injunctive remedy to enforce its interpretation. That independent error merits reversal. Sandoz Br. 43-56; U.S. Br. 33-36.

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[4] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125553Orig1s000NameR.pdf.

A. That Amgen Originally Sought A State Law Injunction Is Irrelevant

Amgen contends (at 42) that the Court "need not decide whether federal law authorizes an injunction to enforce §262(*l*)(8)(A), because Amgen sought an injunction not under federal law but under California's Unfair Competition Law." Even so, the Federal Circuit *issued* its injunction under federal law, as Amgen suggested it could. Amgen CA Br. 58-59. Indeed, the Federal Circuit's federal injunction rendered "moot" Amgen's "appeal from the dismissal of its unfair competition claim" under state law. Pet. App. 27a-28a. That federal injunction is part of the judgment on review, and provides an independent basis for reversal. Sandoz Cert. Reply 10-12. Indeed, it is the law of the Federal Circuit. *Amgen v. Apotex*, 827 F.3d 1052, 1063-64 (Fed. Cir. 2016). Accordingly, AbbVie's suggestion (at 26) that the Court should remand for the Federal Circuit to consider the remedial consequences of its subsection (*l*)(8)(A) interpretation is meritless. The Federal Circuit has already done so, and that injunction's propriety is one of the questions before the Court. Pet. i-ii.

Amgen's attempted retreat to state law suffers from other defects. First, a California cause of action could not support the judgment, as it would have authorized an injunction only for "conduct occurring within California." *Allergan v. Athena Cosmetics*, 738 F.3d 1350, 1360 (Fed. Cir. 2013). Second, because the scope of a state law judgment would be different and because Amgen's cross-petition did not challenge the

affirmance of dismissal of its state law claims based on the notice provision, this Court could not affirm the injunction on state law grounds. *Nw. Airlines v. County of Kent*, 510 U.S. 355, 364-65 (1994). Third, as Sandoz explained in the Federal Circuit, the comprehensive and intricate federal scheme would preempt any such state law claim. Sandoz CA Br. 59; *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 350 (2001); Pet. App. 67a n.4.

B. Amgen Has No Right To A Federal Injunction

Amgen abandons its argument that the injunction here was an injunction pending appeal. Amgen Cert. Opp. 29-30. Instead, Amgen points to the Biosimilars Act's litigation-triggering provisions, contending they authorize an injunction ordering compliance with subsection (*l*)(8)(A). Amgen Br. 45; *see* Genentech Br. 5. But those provisions allow litigation to seek remedies for substantive violations of valid patent rights, not Biosimilars Act procedural violations.

1. A cause of action for patent infringement cannot support an injunction to "enforce" the notice provision

Although Amgen does not cite it, there is a single cause of action under which Biosimilars Act-related litigation may be maintained: 35 U.S.C. § 281. *See* U.S. Br. 4, 6, 16, 18, 22-23. It provides that "[a] patentee shall have remedy by civil action *for infringement* of his patent." 35 U.S.C. § 281 (emphasis added). This cause of action "specifies the conduct for which

defendants may be held liable." *Cent. Bank of Denver v. First Interstate Bank*, 511 U.S. 164, 179 (1994). And the liability-triggering conduct for Section 281 is violation of substantive patent rights—not failure to follow the Biosimilars Act's procedural steps.

Each of the Act's litigation-related provisions controls access to the Section 281 cause of action and shapes the scope of that litigation. Under certain circumstances, for example, the statute makes "submi[ssion]" of a biosimilar application an artificial "act of infringement," actionable under Section 281 where the application's "purpose" is "to obtain approval" of a biologic "*claimed in a patent.*" 35 U.S.C. § 271(e)(2)(C) (emphasis added); *see* U.S. Br. 21-22. Other provisions control the suit's timing, scope, and remedies. 42 U.S.C. § 262(*l*)(2)-(9); 35 U.S.C. § 271(e)(4), (6). But all such litigation necessarily involves a "civil action *for infringement*" of a patent, 35 U.S.C. § 281 (emphasis added), or anticipatory defense to such an action. *Id.* § 271(e)(2); 42 U.S.C. § 262(*l*)(6), (8)(B), (*l*)(9) (all referring to patent infringement actions).

In a properly filed action *for patent infringement* under these provisions, a court would have equitable power to remedy that substantive wrong, *e.g.*, to grant "injunctive relief" against an "infringer" to prevent infringement. 35 U.S.C. § 271(e)(4)(B). But Amgen cites no authority for the proposition that an express cause of action to enforce one requirement (here, prohibition

of patent infringement) authorizes an injunction involving an entirely different one (here, provision of notice).[5]

Indeed, Amgen's cited authority says just the opposite. Amgen Br. 44 (citing *Alexander v. Sandoval*, 532 U.S. 275 (2001)). In *Sandoval* a private cause of action allowed individuals to sue for intentional discrimination. 532 U.S. at 279-80. The Court held, however, that this cause of action did not authorize suit for a *different* violation—disparate impact discrimination. *Id.* at 285-86. The same analysis applies here.

Sandoz explained (at 54-55) that the authority cited in *Apotex* likewise does not support Amgen's mix-and-match approach. Amgen makes no attempt to rehabilitate that precedent, instead citing (at 46) two other decisions (from a purported "legion") supposedly establishing that "courts generally possess power to enjoin violations of the law." But neither decision stands for that breathtakingly broad principle.

In *Califano v. Yamasaki*, it was uncontested that the court had express statutory jurisdiction to review the adequacy of the procedures used to make an administrative determination. 442 U.S. 682, 705 (1979).

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[5] Genentech's reliance (at 26-27) on 35 U.S.C. § 283 is likewise inapposite. That provision authorizes "injunctions in accordance with the principles of equity to prevent the violation of *any right secured by patent*." 35 U.S.C. § 283 (emphasis added); *see Eli Lilly & Co. v. Medtronic, Inc.*, 915 F.2d 670, 674 (Fed. Cir. 1990) (violation of patent right is "necessary predicate" to Section 283 injunction). Subsection (*l*)(8)(A) creates *no* right (Sandoz Br. 44), much less one "secured by patent," 35 U.S.C. § 283.

The Court held that the jurisdictional provision also conferred the power to issue an injunction requiring proper procedures. *Ibid.* In *United States v. Paradise*, 480 U.S. 149 (1987) (plurality), Section 1983 provided an express cause of action for a "suit in equity" for "redress" of constitutional violations. 42 U.S.C. § 1983; *see Paradise v. Prescott*, 767 F.2d 1514, 1516-17 (11th Cir. 1985), *aff'd sub nom. Paradise*, 480 U.S. 149. In both cases (as in those cited in *Apotex*), an express cause of action provided authority to redress *the relevant substantive violation*. Here, there is none.[6]

2. *There is no implied right of action to enforce the notice provision*

Amgen contends (at 50) that even if no express cause of action supports an injunction to enforce the notice provision, the Court should fashion one. Yet Amgen does not come close to justifying creation of a cause of action and injunctive remedy that Congress omitted.

First, as Sandoz showed (at 44), the notice provision creates no private right—it is purely procedural, and the only substantive rights at issue are patent rights. Amgen offers no response. Second, Amgen fails to show congressional intent to create an injunctive

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[6] Nor does the All Writs Act provide such authority. *Contra* Janssen Br. 25; BIO Br. 28. Where, as here (*see* 42 U.S.C. § 262(*l*)(9)(B)), "a statute specifically addresses the particular issue at hand, it is that authority, and not the All Writs Act, that is controlling," even if "compliance with [those] statutory procedures appears inconvenient or less appropriate." *Pa. Bureau of Corr. v. U.S. Marshals Serv.*, 474 U.S. 34, 43 (1985).

remedy. Amgen contends (at 50) that divining such intent "should be straightforward" because the "provision plays an essential role in the procedural framework Congress enacted, and the government does not enforce it." Amgen cites no authority for its "essential role" test, nor does it explain how that standard would be judicially administrable.

Amgen suggests that when Congress regulates conduct between private parties, courts can invent causes of action and remedies—so long as the government plays no enforcement role. Br. 43-44; *see* Genentech Br. 11-15. Amgen cites no authority for such judicial license. It is now recognized as a separation of powers principle that *only* Congress may provide statutory rights and remedies. Congress's decision not to make the Biosimilars Act's procedural steps enforceable by the government (and instead to provide only patent litigation-channeling consequences) does not permit courts to invent their own causes of action and extra-statutory remedies.

a. The statute's express consequences foreclose adding others

The absence of any implied cause of action is confirmed by the Act's express consequences when an applicant does not give notice—a declaratory judgment action by the sponsor, but not the applicant. 42 U.S.C. § 262(*l*)(9)(B); *see* Sandoz Br. 46-47. Amgen's amicus BIO acknowledges (at 26) that Congress intended the declaratory judgment provisions in subsection (*l*)(9) "to penalize and discourage non-compliance by either

party." Congress therefore calibrated the incentives; courts should not invent their own remedies to restrike that balance.

Amgen contends (at 47) that subsection (*l*)(9)(B) "does not purport to *remedy* a marketing-notice violation" but merely "preserv[es] the sponsor's background right to file a declaratory-judgment action." There is no such "background right." It is the Biosimilars Act's artificial infringement provisions that permit pre-approval suits, and subsection (*l*)(9) controls access to them. Sandoz Br. 11. And whether subsection (*l*)(9)(B) is "remedial" is immaterial: Congress anticipated non-provision of notice and expressly provided the consequence. That consequence is not an injunction enforcing notice.

In any event, Amgen misapprehends the statute in asserting that subsection (*l*)(9)(B) is not a "remedy." As Amgen itself recognizes (at 36), notice merely triggers the ability to institute patent litigation: a declaratory judgment (for either applicant or sponsor) or preliminary injunction (for the sponsor). The statute also triggers the ability to pursue certain patent remedies if the applicant does *not* give notice: the sponsor, but not the applicant, may seek a declaratory judgment and injunctive relief on certain patents. 42 U.S.C. § 262(*l*)(9)(B); *see* 28 U.S.C. § 2202. Thus, the statutory consequence for not satisfying one provision that would have triggered patent litigation (subsection (*l*)(8)(A)) is to trigger patent litigation a different way (subsection (*l*)(9)(B)). Congress's specification of that alternative pathway to patent remedies forecloses

Amgen's judge-made, non-patent-based injunction. *Karahalios v. Nat'l Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989).

Contrary to Amgen's contention (at 50), adhering to the statute's specified consequences does not render the notice provision a "nullity." If the applicant does not provide notice, it cannot obtain patent certainty by seeking a declaratory judgment on any unlitigated patents. *Compare* 42 U.S.C. § 262(*l*)(9)(A) (notice lifts bar on actions by sponsor *and* applicant), *with id.* § 262(*l*)(9)(B) (failure to give notice lifts bar only for sponsor). If the sponsor does not seek a declaratory judgment, the applicant may be forced to launch at risk, without knowing whether it faces damages. If any significant patents remain, an applicant would have powerful incentives to provide notice.

Amgen also contends (at 47) that subsection (*l*)(9)(B) "would be a wholly ineffective remedy for a marketing-notice violation." This policy-based objection is misplaced. *Sandoval*, 532 U.S. at 286-87 ("courts may not create" a cause of action, "no matter how desirable that might be as a policy matter, or how compatible with the statute"). In any event, there are myriad real-world ways that a sponsor will learn of pending biosimilar applications before FDA approval. Sandoz Br. 48-51; Biosimilars Council Br. 28-30, 34-35. Armed with such knowledge, sponsors could simply ask applicants if they intend to provide notice. If an applicant's answer were unsatisfactory, a sponsor would have a good-faith basis for asserting the applicant was going to "fail[] to complete an action"

required by subsection (*l*)(8)(A) and could bring a pre-launch infringement action for declaratory judgment (and, if necessary, a patent-based preliminary injunction). 42 U.S.C. § 262(*l*)(9)(B); 28 U.S.C. § 2202; 35 U.S.C. § 283; *infra* pp. 40-41.

Finally, Amgen observes (at 48-49) that the subsection (*l*)(9)(B) consequence for not providing notice is inapplicable where the applicant withholds its application. But under those circumstances, subsection (*l*)(9)(C) has *already* authorized sponsors to seek a declaratory judgment on all patents. Amgen contends (at 49) that the lack of an *additional* consequence permits courts to fashion one. Again, however, the point of all these provisions is simply to trigger and channel patent litigation. When a sponsor already may sue on all patents, Congress concluded there is no need for additional patent litigation-channeling consequences. Sandoz Br. 60-63 (explaining notice provision inapplicable in these circumstances).

b. Congress elsewhere provided for an injunction but not in subsection (l)(8)

Sandoz explained (at 51-52) that the statute elsewhere expressly authorizes an injunction, which confirms that no injunction is available to enforce the notice provision. The statute provides that violation of certain confidentiality provisions "shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to

be an appropriate and necessary remedy for any violation or threatened violation." 42 U.S.C. § 262(*l*)(1)(H). Amgen argues (at 50) that this provision does not provide a remedy but merely "tells courts how to *apply* the traditional factors for equitable relief." It is difficult to construe a provision expressly stating that "injunctive relief" is both "appropriate and necessary" as anything but an authorization to provide it. Regardless, the absence of any analogue in the notice provision is powerful evidence that Congress did not intend an injunction to be available.

C. By Delaying Launch Of Every Biosimilar By 180 Days, The Federal Circuit's Ruling Disrupts The Careful Balance Congress Struck

As Sandoz showed (at 56-60), the Federal Circuit's decision delays all biosimilars' introduction by 180 days. Given Congress's intense focus on the length of the exclusivity period during the legislative process, Congress could not have silently intended the 12-year period to be 12 years and 180 days. *Ibid.*; Biosimilars Council Br. 14-17.

The statute provides that a biosimilar license may be made "effective" 12 years after the first licensure of the reference product, 42 U.S.C. § 262(k)(7)(A), and that a biosimilar may be introduced once a license is "in effect," *id.* § 262(a)(1)(A). Yet, under Amgen's reading, no biosimilar could ever be introduced at 12 years—all would have to wait until 12 years plus 180 days. Sandoz Br. 56-57. Amgen responds (at 52) that

the "approval remains effective" during the 180 days but that "it is only a necessary condition" for marketing, "not a sufficient one." But it would have been bizarre for Congress to use the word "effective" to describe a license that would always be *in*effective for 180 days.

Amgen also states (at 52) that "there is nothing unusual about delaying the market entry of a drug to facilitate orderly patent litigation" and points to Hatch-Waxman, which provides an "automatic stay of FDA approval" for adjudication of patent claims. This proves Sandoz's point. Had Congress intended an analogous stay of FDA approval here, it would have provided one expressly. Instead, "Congress declined to link FDA approval to a single provision in subsection (*l*)." Pet. App. 53a (Chen, J., dissenting). Moreover, the 180-day stay would perversely apply even when there are *no* patents to litigate. Sandoz Br. 40-41; Apotex Br. 19-20.

Amgen contends that "Sandoz and its corporate parent (Novartis) proposed precisely such a system" of delayed marketing "during the legislative process." Br. 53. This is just one example of so-called "legislative history" on which Amgen and its amici rely. This Court recently emphasized that "floor statements by individual legislators rank among the least illuminating forms of legislative history." *NLRB v. SW Gen.*, No. 15-1251, slip op. at 16 (Mar. 21, 2017). Yet Amgen and its amici rely on even less illuminating sources: witness statements at hearings before earlier Congresses, *e.g.*, Amgen Br. 10, 62, and earlier unenacted bills,

e.g., Amgen Br. 9, 45. Even if considered, Novartis's letter would be irrelevant. It addressed a fundamentally different proposal to have *no* pre-approval resolution of patent disputes. Ltr. From Paulo Costa, Novartis Corp., to Reps. Pallone & Deal 26-27 (May 1, 2008). Congress rejected that approach, providing for patent dispute resolution *before* licensure.

Moreover, if other such statements were considered, they would support Sandoz's reading. In discussing a predecessor bill, Representative Eshoo, the Biosimilars Act's principal sponsor, stated that the bill was intended to "ensure that all patent disputes involving a biosimilar are resolved *before, and I emphasize the word before*, the expiration of the data-exclusivity period." *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 9 (2009) ("*Biologics and Biosimilars Hearing*") (emphasis added). A representative of Amgen's amicus BIO similarly stated that "[n]early all stakeholders in the biosimilar debates support inclusion of procedures to identify and resolve patent issues *before a biosimilar is approved*." Jeffrey P. Kushan, Prepared Statement on Behalf of Biotechnology Indus. Org., *Biologics and Biosimilars Hearing* 77 (emphasis added). Such statements refute Amgen's portrayal of congressional intent to channel litigation *after* FDA approval.

Amgen notably does not endorse what it calls the Federal Circuit's "speculat[ion]" in *Apotex* that "the FDA might be able to 'issue a license before the

11.5-year mark and deem the license to take effect on the 12-year date,' allowing the applicant to give its marketing notice 180 days before the end of the 12-year period." Br. 56 (quoting 827 F.3d at 1062). Nor does Amgen respond to Sandoz's explanation (at 58-59) why that would not restore the 12-year exclusivity period Congress intended. Moreover, even if feasible, the Federal Circuit's workaround would apply only where the application was approved during the exclusivity period. That is a distant prospect—"[t]oday, many biosimilar applications are pending for blockbuster biologics where the statutory market exclusivity has already expired." Coherus Br. 13-14.

III. THE FEDERAL CIRCUIT ERRONEOUSLY DIVORCED THE NOTICE PROVISION FROM THE PATENT RESOLUTION SCHEME

Sandoz and the government each showed in standalone sections of their briefs (Sandoz Br. 60-63; U.S. Br. 32-33) that the notice of commercial marketing provision is inapplicable where, as here, the parties did not engage in the information exchange process. Pet. App. 48a-52a (Chen, J., dissenting). And Sandoz explained (at 6-7, 60) this interpretation independently warrants reversal. Amgen offers no response.

RESPONSE IN NO. 15-1195

SUMMARY OF ARGUMENT

I. Read in the context of the entire Biosimilars Act, the "shall" provision in Section 262(*l*)(2)(A) is a condition precedent to engaging in the information exchange process, not a mandatory requirement in all circumstances. To take advantage of that exchange process, the applicant must provide the sponsor its application within 20 days of notice that the FDA has accepted it for review. This interpretation is consistent with uses of "shall" in subsection (*l*), as well as in other statutory schemes.

This reading also furthers Congress's carefully reticulated system for early litigation of any patent rights. Congress balanced the interests between sponsors and applicants, determined what the consequences of noncompliance should be at each step of the process, and allowed the parties to weigh the benefits and burdens of each option. Congress determined that if the application is not provided, allowing the sponsor to bring an immediate infringement action is the proper recourse. Sandoz did not act unlawfully in taking a path expressly laid out by Congress.

II. Even if subsection (*l*)(2) is mandatory in all circumstances, a sponsor would not be entitled to an extra-statutory injunction to "enforce" it. Courts may not fashion causes of action and injunctive remedies on top of the consequences Congress provided.

ARGUMENT

I. THE BIOSIMILARS ACT DOES NOT MANDATE THAT THE INFORMATION EXCHANGE PROCESS BE FOLLOWED IN ALL CIRCUMSTANCES

The Court does not interpret a statutory provision "in isolation." *Star Athletica v. Varsity Brands*, No. 15-866, slip op. at 6 (Mar. 22, 2017). Instead, it "look[s] to the provisions of the whole law to determine [the provision's] meaning." *Id.* at 7 (quotation marks and citation omitted). Applying these principles, the court of appeals correctly concluded that "Sandoz did not violate the BPCIA by not disclosing its [application] and the manufacturing information according to § 262(*l*)(2)(A)." Pet. App. 27a. Because Amgen's state law claims required an unlawful act, the court of appeals correctly affirmed their dismissal. Pet. App. 26a-27a, 28a-29a.

A. Text And Structure Demonstrate That "Shall Provide" In Section 262(*l*)(2)(A) Is A Mandatory Condition Precedent

1. Subsection (l)(2)(A) is a condition precedent to the information exchange process

The Act's patent resolution regime goes well beyond the Section 262(*l*) information exchange process on which Amgen focuses. As Sandoz explained (at 10-17), the Act made interlocking amendments to Titles 28, 35, and 42, creating new artificial acts of infringement to allow early resolution of patent

disputes before *actual* infringement. The actions and inactions of the applicant and sponsor determine which party can sue under these provisions, as well as any suit's scope and timing. Sandoz Br. 10-17. Regardless of the paths taken, the ultimate destination is the same: patent litigation.

One route to pre-approval litigation is to complete the information exchange process. To start it, the applicant "shall provide to the reference product sponsor a copy of the application submitted" within 20 days of the FDA's acceptance of the application. 42 U.S.C. § 262(*l*)(2)(A). But the Act expressly contemplates that an applicant might not do so. In that event, nonprovision of the application is an act of artificial infringement; the information exchange process does not happen; and the sponsor may sue immediately, as Amgen did here. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii); *see* CA JA A79-A80. Rather than allowing parties to compel compliance, the statute incentivizes their participation in the process. Pet. App. 71a; *infra* pp. 35-36.

2. *Amgen improperly focuses on words in isolation*

"Shall." Amgen relies principally (at 58) on the notion that "'shall' is ordinarily 'the language of command.'" But an interpretation that is "plausible in the abstract" fails when it is "ultimately inconsistent with both the text and context of the statute as a whole." *Sturgeon v. Frost*, 136 S. Ct. 1061, 1070 (2016). Despite its supposed embrace (at 1) of the statute "as written,"

Amgen disregards the statute's specification of what follows when a "shall" condition is not satisfied.

Sandoz agrees that "shall" in Section 262(*l*)(2)(A) is mandatory. It specifies an action that an applicant *must* take to proceed with the process: *if* an applicant wishes to engage in the information exchange, it "shall" timely provide its application. 42 U.S.C. § 262(*l*)(2)(A); *see* Pet. App. 69a. When that condition is unsatisfied, the parties shift to a different patent resolution track. "*If* a subsection (k) applicant fails to provide [its] application," 42 U.S.C. § 262(*l*)(9)(C) (emphasis added), the sponsor may immediately commence a declaratory judgment action under the artificial act of infringement provision created for precisely that circumstance. Pet. App. 15a-17a; 35 U.S.C. § 271(e)(2)(C)(ii).

This reading is confirmed by Section 262(*l*)(6), which provides that after the information exchange process, "the reference product sponsor *shall* bring an action for patent infringement" on specified patents within 30 days. 42 U.S.C. § 262(*l*)(6) (emphasis added). If "shall" were mandatory in all circumstances, then a sponsor failing to timely sue would "violate" subsection (*l*)(6). That cannot be right. Congress obviously did not make it "unlawful" not to file a lawsuit. Indeed, compelling such protected activity would create serious constitutional concerns. *Cf. Bill Johnson's Restaurants v. NLRB*, 461 U.S. 731, 741 (1983).

Instead, the statute incentivizes sponsors to sue within 30 days by providing consequences if they do

not. Expressly envisioning that a sponsor might not sue until "*after* the expiration of the 30-day period," the statute limits the sponsor's remedies in that event. 35 U.S.C. § 271(e)(6)(A)(ii)(I), (B) (emphasis added). Thus, the requirement that a sponsor "shall" sue within a specified timeframe is a condition precedent to other statutory benefits. *Id.* § 271(e)(4), (6)(B). So too with the "shall" provision in subsection (*l*)(2).

"***May.***" Amgen contends (at 58-59) that its view is supported by the "contrast" between the statute's use of "shall" and "may"; its description of provision of the application as "required"; and its reference to non-provision as a "fail[ure]." These arguments again ignore the broader context.

Subsection (*l*)(2) uses "shall" and "may" to distinguish between the information that "shall" be provided as a condition precedent to participating in the information exchange, 42 U.S.C. § 262(*l*)(2)(A), and the additional information that "may" be optionally provided but is not necessary to proceed to the next step, *id.* § 262(*l*)(2)(B). Similarly, the statute uses "required" to describe the same, condition-precedent-satisfying information. *Id.* § 262(*l*)(1)(B)(i); *id.* § 262(*l*)(9)(A), (C).

"***Fails.***" Nor by describing noncompliance as a "fail[ure]" does the statute mandate the provision of subsection (*l*)(2)(A) information in all circumstances. *Id.* § 262(*l*)(9)(C). The statute uses "fails to provide the application" and "application not provided" interchangeably. *Ibid.* ("Subsection (k) application not provided—If a subsection (k) applicant fails to provide the

application * * *"). Elsewhere it uses "fail" when there plainly is no duty to perform. Subsection (*l*)(4)(B), titled "Failure to reach agreement," discusses what happens if the parties "fail to agree" on a patent list. *Id.* § 262(*l*)(4)(B). Yet there is certainly no means to compel agreement. Instead—just as when an applicant "fails" to provide its application—the parties' "[f]ailure" to agree simply shifts them to a different patent resolution track. *Id.* § 262(*l*)(5) (titled "Patent resolution if no agreement").

This same contingent structure pervades subsection (*l*): multiple "shall" provisions are coupled with statutory consequences for noncompliance. Sandoz Br. 12 (flowchart).

"Must" in discovery rules. Amgen points to a discovery rule stating that a party in pending litigation "'*must*, without awaiting a discovery request, provide' certain information." Br. 60 (quoting Fed. R. Civ. P. 26(a) (emphasis by Amgen)). But whether that rule is "mandatory" says nothing about the meaning of the Biosimilars Act. Moreover, the discovery rules expressly provide what the Biosimilars Act does not—a provision allowing parties to request the court "to compel disclosure." Fed. R. Civ. P. 37(a)(3)(A).

More analogous are statutes and rules mandating that a party act by a deadline—or else suffer consequences. For example, one of this Court's jurisdictional statutes provides that a direct appeal "*shall be taken* within thirty days after the entry" of an order. 28 U.S.C. § 2101(a) (emphasis added); *see also, e.g.*,

Fed. R. App. P. 4(b)(1)(A) ("a defendant's notice of appeal *must be filed* in the district court within 14 days after the later of" certain events). But a party failing to take such an appeal is not "violating" that provision, nor could it be compelled (under federal or state law) to appeal. Rather, the party would suffer the consequences of failing to do so, by having any late appeal dismissed and the underlying order left undisturbed. *Bowles v. Russell*, 551 U.S. 205, 211-13 (2007).

B. Interpreting Section 262(*l*)(2)(A) As A Condition Precedent Advances The Biosimilars Act's Purposes

1. Congress carefully balanced the interests of sponsors and applicants

Reading Section 262(*l*)(2)(A) as a condition precedent to one path to patent litigation fulfills Congress's purpose: pre-approval litigation on potential patent rights. Congress demonstrated its purpose by creating acts of artificial infringement—both for when the information exchange takes place *and* for when it does not. 35 U.S.C. § 271(e)(2)(C).

This regime offers tradeoffs for both sponsors and applicants. Where, as here, the applicant does not participate in the information exchange process, there are benefits to the sponsor and costs to the applicant. The sponsor gains far more control over the scope and timing of any infringement suit. It can sue immediately on all its patents. Or the sponsor can wait until the biosimilar's approval, forcing the applicant to launch its product without knowing whether it faces

patent damages. 42 U.S.C. § 262(*l*)(9)(B)-(C); 35 U.S.C. § 271(e)(2)(C)(ii). The applicant forfeits its ability to gain certainty by filing its own declaratory judgment action and its pre-litigation look at potentially relevant patents. 42 U.S.C. § 262(*l*)(3)(A), (9)(C). An applicant may nevertheless choose this path if it seeks quick resolution, believes that no unexpired, relevant patents will remain after the exclusivity period, and/or has concerns about providing its application without a court protective order. Pet. App. 72a.

By contrast, participating in the information exchange process benefits applicants. As Amgen's amicus acknowledges, it gives "applicants significant control over the timing and scope of patent litigation." BIO Br. 23. Not only does that path give the applicant a temporary safe harbor from litigation, 42 U.S.C. § 262(*l*)(9)(A), but it forces the sponsor to identify the patents it believes are valid and infringed or forfeit its ability to sue for infringement, *id.* § 262(*l*)(3)(A); 35 U.S.C. § 271(e)(6)(C). It allows the applicant to control how many patents are initially litigated. 42 U.S.C. § 262(*l*)(4), (5). And following the process increases the chance of an infringement suit by the sponsor within a specified timeframe, because otherwise its remedies would be limited. *Id.* § 262(*l*)(6); 35 U.S.C. § 271(e)(6)(B).

2. *Amgen's resort to policy arguments and faux "legislative history" is unavailing*

In arguing for its rigidly separated two-phase mandatory system, Amgen advances policy arguments unmoored from the statute and cites unenacted bills from previous Congresses.

First, Amgen posits (at 60-61) that if an applicant does not initiate the information exchange process by providing its application, a sponsor might not know which patents the biosimilar would infringe. But Congress concluded otherwise, expressly giving the sponsor the immediate right to sue for artificial infringement if the application is not provided. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). Amgen did exactly that here. CA JA A79-A80 (infringement claim).

Contrary to Amgen's assertions (at 61), such a suit will protect any valid patent claims. Like all other patentee plaintiffs, a sponsor will have access to normal discovery tools. The sponsor can obtain the biosimilar application under a protective order, just as Amgen did here. Pet. App. 17a. Competitors rarely have access to each other's confidential manufacturing processes before litigating. Indeed, knowing that the applicant's biologic is similar enough to qualify as a biosimilar gives the sponsor more information than the ordinary competitor, not less. *Contra* Amgen Br. 61. And competitors regularly file infringement suits after diligent investigation, such as pre-suit letters seeking information about manufacturing processes. If the

response is inadequate, the patentee can sue without violating Federal Rule of Civil Procedure 11. *Hoffman-La Roche v. Invamed*, 213 F.3d 1359, 1363-65 (Fed. Cir. 2000). Then patentees use discovery to learn detailed information and amend their complaint if necessary. Pet. App. 17a, 72a n.6; Biosimilars Council Br. 31-33.[7]

Second, Amgen contends (at 62) that the applicant must always produce its application because the disclosures facilitate the later information exchange steps, which can streamline litigation. To start, there is nothing streamlined about allowing parties to sue every 60 days to challenge the other side's compliance with the information exchange. *E.g.*, Compl., *Genentech v. Amgen*, No. 1:17-cv-165 (D. Del. 2017) (suit to force *Amgen* to provide more information under subsection (*l*)(2)(A) about Amgen's biosimilar). Moreover, Amgen's position ignores that Congress envisioned more than one path to litigation. Sandoz Br. 12. And as the district court recognized, a forced march through the information exchange (even without pit-stops for injunction litigation) may sometimes be inefficient. Pet. App. 72a.

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[7] Amgen's discussion (at 61-62) of its suit against Hospira is immaterial. Amgen sued Hospira under subsection (*l*)(6) on two patents. Amgen CA Br. 4-12, Dkt.28, No. 2016-2179 (Fed. Cir. Sept. 12, 2016). Yet Amgen sought discovery regarding possible infringement of *different* patents, on which it could not sue because of their absence from its subsection (*l*)(3) list. *Ibid.*; *see* 42 U.S.C. § 262(*l*)(6). By contrast to the limited scope of a subsection (*l*)(6) suit, a declaratory judgment suit triggered by non-provision of the application can involve any patent (if there is a product or use patent), Sandoz Br. 13, so discovery would not be similarly constrained.

Where, as here, an applicant "values expedience over risk mitigation," the statute allows it to forgo the process and subject itself to immediate suit. *Ibid.* The information exchange process "could take up to 230 days" after the application is provided—"just to *commence* patent litigation." *Ibid.* (emphasis added). Sandoz therefore "traded in the chance to narrow the scope of potential litigation with Amgen through subsection (*l*)'s steps, in exchange for the expediency of an immediate lawsuit." Pet. App. 73a.[8]

Third, Amgen asserts (at 62) that allowing an applicant to forgo the information exchange would "unfairly limit the sponsor's remedies" because the injunction authorized by 35 U.S.C. § 271(e)(4)(D) is otherwise unavailable. Amgen's characterization (at 63) of this provision as providing a "mandatory" injunction is contrary to this Court's consistent direction that injunctions require examination of "traditional equitable considerations." *eBay*, 547 at 392-93.

Regardless, the Section 271(e)(4)(D) injunction is available only in limited circumstances: when patent litigation proceeds to a final decision from

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[8] BIO contends (at 23) the need for expediency is diminishing. That is wrong. Most biosimilars in development reference biologics for which exclusivity has run. *Supra* p. 29. And whenever the applicant believes all relevant patents will have expired during the 12-year exclusivity period (which was intended to mirror patent protection, Sandoz Br. 10), it might forgo the information exchange.

the Federal Circuit before the exclusivity period expires. 35 U.S.C. § 271(e)(4)(D) (cross-referencing 42 U.S.C. § 262(k)(6)-(7)). Amgen's exclusivity expired long ago, so it could not have accessed this provision even if Sandoz had provided its application. Moreover, the statute separately allows injunctions for patent infringement, *id.* § 271(e)(4)(B)—without any condition precedent related to the information exchange process.

Finally, Amgen contends (at 63) that "Congress considered and rejected a permissive rather than mandatory" scheme. But unenacted legislation from previous Congresses sheds no light here. *Star Athletica*, slip op. at 17 (arguments from unenacted bills "lack[] persuasive significance in most circumstances") (quotation marks and citation omitted). Those bills proposed a very different information exchange process and, unlike the Biosimilars Act, created no consequences for the applicant's decision not to initiate or complete it. *Compare* 42 U.S.C. § 262(*l*)(9)(B), (C), *with* H.R. 6257, H.R. 1427, S. 623.

II. NO EXTRA-STATUTORY RIGHT OF ACTION TO COMPEL PROVISION OF THE BIOSIMILAR APPLICATION EXISTS

Even if disclosure of the application were mandatory, a sponsor cannot secure an injunction mandating disclosure. The statute creates no cause of action for that remedy.

Amgen contends (at 64) that the Court need not decide whether a federal injunction is available

because it sought a state law injunction. But Amgen fails to note (and thus waives any challenge to) the Federal Circuit's conclusions that such an injunction is unavailable on state law grounds. Pet. App. 27a, 29a.[9] Sandoz opposed Amgen's conditional cross-petition on that basis. 15-1195 Opp. 24-32. If the Court granted the cross-petition to decide whether federal law authorizes an injunction to "enforce" subsection (*l*)(2), it should answer that question "no" and affirm.

As it does for subsection (*l*)(8)(A), Amgen contends (at 64-65) that courts have "inherent power to grant equitable relief" to enforce subsection (*l*)(2) and, in the alternative, that a private right of action should be inferred. Those arguments fail for the reasons above. *Supra* pp. 20-28.

Implying a private right of action to "enforce" subsection (*l*)(2) would be particularly inappropriate given that Congress expressly specified consequences for non-provision of the application: an artificial act of infringement allowing immediate patent litigation by the sponsor, 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). *Supra* pp. 33-34.

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[9] Moreover, any attempt to use California law to "enforce" the Biosimilars Act would be preempted and would in any event support an injunction only in California. *Supra* pp. 19-20.

Amgen complains (at 65) these provisions do not "provide any remedy" for a "violation" of subsection (*l*)(2)(A). This complaint lacks merit for the same reasons as it did for subsection (*l*)(8)(A). *Supra* pp. 25-26. Regardless whether these provisions are themselves "remedial," they specify the only consequences Congress provided for noncompliance with subsection (*l*)(2): access to litigation to obtain *patent remedies*. Indeed, Congress specified that patent remedies are "the *only* remedies which may be granted by a court" for an artificial act of infringement under the Biosimilars Act. 35 U.S.C. § 271(e)(4) (emphasis added). In a scheme that "concerns one thing: patent litigation," Pet. App. 45a (Chen, J., dissenting), those remedies are fully adequate.

CONCLUSION

The Federal Circuit's judgment on the notice of commercial marketing should be reversed. Its judgment on the biosimilar application should be affirmed.

Respectfully submitted,

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MARCH 31, 2017

RECORD
AND
BRIEF

Nos. 15-1039 and 15-1195

Supreme Court, U.S.
FILED
DEC 20 2016
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Cross-Petitioners,

v.

SANDOZ INC.,

Cross-Respondent.

ON PETITION AND CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SUPPLEMENTAL BRIEF FOR RESPONDENTS AND CROSS-PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondents Amgen Inc. and Amgen Manufacturing Limited state the following:

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with a 10% or greater ownership in Amgen Manufacturing Limited.

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SUPPLEMENTAL BRIEF FOR RESPONDENTS AND CROSS-PETITIONERS

The Government would render the patent provisions of subsection 262(*l*) a dead letter. It contends that an Applicant cannot be compelled to comply with either subparagraph 262(*l*)(2)(A) or subparagraph 262(*l*)(8)(A). (*See* U.S. Br. 13, 21.) On the Government's reading, unless an Applicant happens to have securities-law disclosure obligations, it may keep secret the fact it has filed an aBLA, refuse to provide notice, and surprise the Sponsor and the courts when the FDA eventually announces it has licensed the Applicant's biosimilar. While the Government asserts that subsection 262(*l*) was intended to accelerate patent litigation, its reading of the statute would permit Applicants to delay that litigation until commercial marketing begins and promote launch-at-risk tactics that threaten continuity of patient care.

That is an untenable reading of the BPCIA. It would wreak havoc on the market, on Sponsors, and on the federal courts. Nothing in the text of the statute, its surrounding context, or the purpose of the statute supports that reading. It defies logic that Congress would wrestle for years over biosimilar legislation and enact an intricate, integrated statute that is rendered optional simply by limiting the scope of declaratory-judgment actions.

The flaws in the Government's interpretation reinforce all the other reasons that the Court should deny Sandoz's petition and leave undisturbed the Federal Circuit's unanimous holding that the 180-

day notice of commercial marketing may be given only after FDA licensure.[1] (*See* Pet. App. 18a-22a.) At a minimum, the Government's inconsistent statements and omissions demonstrate the need for further percolation. This was the first case to address the patent provisions of subsection 262(*l*), and although the panel's decision now governs the specific questions that were before it, future cases will shed additional light on the statute and how its various pieces work together. Until that occurs, this Court's involvement would be premature and could produce unintended consequences.

If, however, the Court grants Sandoz's petition, it should also grant Amgen's conditional cross-petition. Indeed, the Government recommends granting Amgen's conditional cross-petition to review the integrated provisions of subsection 262(*l*) together to "ensure that the parties would be able to raise the full set of arguments in support of their positions." (U.S. Br. 24; *accord id.* at 1, 12-13.) Although the real lesson is that review should be denied entirely at this time, the Government is correct that if the Court takes one part of the case, it should also grant Amgen's conditional cross-petition.

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[1] The Government's brief could be read to suggest that Judge Chen dissented from the entirety of the Panel's decision regarding subparagraph 262(*l*)(8)(A). (*See* U.S. Br. 11-12.) The panel was unanimous that notice is effective only if given after FDA licensure. Judge Chen's dissent addressed whether an Applicant that fails to provide the subparagraph 262(*l*)(2)(A) disclosure must still give that notice.

I. THE GOVERNMENT'S BRIEF REINFORCES THAT THE COURT SHOULD DENY SANDOZ'S PETITION

A. The Federal Circuit Correctly Construed Subparagraph 262(*l*)(8)(A) and There Is No Reason To Grant Sandoz's Petition

1. The Text of Subparagraph 262(*l*)(8)(A) Demonstrates That Notice of Commercial Marketing Must Follow FDA Licensure

Subparagraph 262(*l*)(8)(A) provides that the Applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." This Court's review of that provision would necessarily begin with its language, yet the Government all but ignores the verb in the sentence. It never cites or distinguishes any of this Court's clear precedents establishing that the verb "shall" is generally mandatory. *See, e.g., Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Lopez v. Davis*, 531 U.S. 230, 241 (2001); *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359-60 (1895).

Nor does the Government offer any satisfactory explanation for why Congress used the words "the biological product licensed under subsection (k)" in this provision but elsewhere in subsection 262(*l*) always refers to the product that "is the subject of" the subsection (k) application. *See* 42 U.S.C. §262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B). The Government suggests that "product licensed" is used because the

product will be licensed when commercial marketing begins. (*See* U.S. Br. 14.) That is inherent; marketing without licensure is illegal. If subparagraph 262(*l*)(8)(A) ended ". . . before the date of the first commercial marketing of the biological product that is the subject of the subsection (k) application," marketing would still have to follow licensure, and thus this argument cannot explain Congress's word choice.

The careful distinction in Congress's word choice is reinforced by provisions of the BPCIA that the Government ignores: subparagraphs 262(k)(6)(A) and (C)(ii). (*See* Amgen Opp'n 18-19.) Those provisions help define the length of exclusivity as against other biosimilar products that is afforded to the first biosimilar that demonstrates "interchangeability" with respect to the reference product. Here, "commercial marketing" and "approval" are used with respect to the same product, and they suggest that commercial marketing will follow approval by six months. That provides strong support for the 180-day notice in subparagraph 262(*l*)(8)(A) being given after FDA licensure, yet the Government makes no attempt to square its reading with these provisions.

2. Subparagraph 262(*l*)(8)(A) Does Not Confer Six Months of Exclusivity

The Government argues that because the timing of market entry for biosimilars was "a significant issue addressed by the BPCIA," and given the 12-year exclusivity period in paragraph 262(k)(7), it is "particularly unlikely that Congress would have further delayed biosimilars' marketing in such an

indirect manner" as to require the 180 days' notice to be given after FDA licensure. (U.S. Br. 14-15.)

The Federal Circuit rightly rejected this argument. Subparagraph 262(*l*)(8)(A) does not confer "exclusivity." Instead, the 180-day notice period helps ensure an orderly litigation process, even when, for example, the BPCIA is applied retroactively to biologic products that had been on the market more than 12 years when the BPCIA was enacted.

Moreover, even during the twelve-year data "exclusivity" period of paragraph 262(k)(7), another company may obtain FDA approval of its version of a biologic product under the traditional subsection 262(a) pathway, using its own clinical efficacy and safety data. Indeed, another pharmaceutical company, Teva, did that for filgrastim, obtaining approval of its filgrastim product, GRANIX®, under subsection 262(a). (*See* Amgen Opp'n 23.)

Nor does the 180-day-notice requirement under subparagraph 262(*l*)(8)(A) extend even the limited data exclusivity provided during the 12-year period. The notice requirement is specific to each individual Applicant. For example, if the FDA ever approves Apotex's proposed biosimilar filgrastim product, Amgen will continue to face competition from both Sandoz's ZARXIO® and Teva's GRANIX® products while Apotex gives 180 days' notice to facilitate an orderly preliminary-injunction process. Amgen will enjoy no market exclusivity during that period.

Nor would there be anything unusual about delays of market entry extending beyond the expiration of a data-exclusivity period. The Hatch-

Waxman Act, which the Government contends is "analogous to" aspects of the BPCIA (U.S. Br. 2), grants periods of data exclusivity with respect to chemical medicines, 21 U.S.C. § 355(j)(5)(F)(ii), (iii). It also provides for a stay of FDA approval of a generic's ANDA lasting up to 30 months if the patent owner commences timely litigation. *Id.* § 355(j)(5)(B)(iii). The 30-month stay can, and often does, cause a product to remain off the market past the expiration of the data-exclusivity periods. The 180-day notice provision of subparagraph 262(*l*)(8)(A) is considerably more modest than the 30-month stay under the Hatch-Waxman Act.

The Government expresses concern that an Applicant with a new biosimilar license might have to "wait 180 days after FDA has authorized it to commence marketing, even if the sponsor had no arguably valid infringement claim to warrant such delay." (U.S. Br. 14.) The Government wrongly assumes that the list of potentially applicable patents is fixed at the end of the information exchange under paragraph 262(*l*)(3) or the filing of litigation under paragraph 262(*l*)(6). That ignores paragraph 262(*l*)(7). If a patent is newly issued to, or newly exclusively licensed by, the Sponsor after it has provided the subparagraph 262(*l*)(3)(A) list, the Sponsor must supplement that list within 30 days, triggering further information exchange. *See* 42 U.S.C. § 262(*l*)(7). Such a patent is then explicitly included within subparagraph 262(*l*)(8)(B), which the Government overlooks.

3. The "Fully Crystallized Controversy" Refers to the Need for a Preliminary Injunction

The Government goes to great length to criticize the Federal Circuit's observation that requiring notice after FDA licensure would help ensure a "fully crystallized controversy," but its criticism misconceives the purpose of the provision and the Federal Circuit's logic.

The Government conflates judicial resolution of substantive patent disputes with the grant of an injunction. It notes that because the Applicant could, if it chose, force all of the patents listed on the subparagraph 262(*l*)(3)(A) and (*l*)(3)(B) lists to be included in what it calls the "Round 1 litigation," there is already a fully crystalized, litigable controversy on all of those patents long before FDA licensure. (U.S. Br. 15-16.)

That wrongly equates the existence of an Article III controversy with the availability of equitable relief. The reason that there is a controversy sufficient to support patent-infringement litigation is that Congress made the filing of an aBLA under the subsection 262(k) pathway an act of infringement, either for the patents listed by the Sponsor and Applicant in the paragraph 262(*l*)(3) exchanges or, if the Applicant fails to provide its subparagraph 262(*l*)(2)(A) disclosure, for any patent the Sponsor could have listed in those exchanges. *See* 35 U.S.C. § 271(e)(2)(C)(i), (ii).

Whether there is a basis to sue on a technical act of infringement, however, is a very different inquiry

than the public-interest-oriented and litigant-specific factors that a district court must consider in deciding whether to grant injunctive relief. Among those factors are the irreparability of harm in the absence of preliminary relief, the public interest, and the likelihood of success on the merits. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). That is why the Federal Circuit referred to a "fully crystallized controversy regarding the need for injunctive relief." (Pet. App. 21a (emphasis added).) Tellingly, the Government omits the underlined words. The 180-day notice requirement, as interpreted by the Federal Circuit, provides the Sponsor and the courts with critical information and certainty regarding when the biosimilar will actually be first commercialized and, by virtue of the FDA license, what the biosimilar is, how it will be made, and for what therapeutic uses it will be sold. As the Federal Circuit explained, "[w]e believe that Congress intended the notice to follow licensure, at which time the product, its therapeutic uses, and its manufacturing processes are fixed." (*Id.*) All of those facts, which crystallize only at final approval, inform whether there is imminent need for judicial action, providing a concrete basis for application of the preliminary-injunction factors. Allowing an Applicant to provide notice long before its application is approved by the FDA would defeat that purpose.

4. If Notice Cannot Be Enforced, Then Notice Is Illusory

The Government contends that "no federal cause of action exists under which a sponsor could obtain

injunctive relief if the applicant fails to give notice as specified in Section 262(*l*)(8)(A)." (U.S. Br. 13.) That position is in tension with the many places where the Government touts the virtue of pre-marketing notice. (*See, e.g.*, *id.* at 17-18.) The Government recognizes, for example, that "Congress concluded that a sponsor should be given a fair chance to litigate the Round 2 patents prior to actual marketing" and that "Subsection (*l*)(8)(A)'s notice requirement therefore is properly viewed as affording the sponsor an adequate opportunity to commence litigation on the Round 2 patents" for which it could not sue during what the Government calls "Round 1." (*Id.* at 18.)

If an Applicant cannot be compelled to provide the 180-day notice, then those Congressional purposes are gutted. An Applicant could provide its aBLA under paragraph 262(*l*)(2), exchange information under paragraph 262(*l*)(3), defer until Round 2 all but one of the listed patents under paragraph 262(*l*)(5), wait until it obtains FDA licensure to announce that it was refusing to provide notice under subparagraph 262(*l*)(8)(A), and then immediately begin commercial marketing. The Sponsor would have to seek a temporary restraining order, having lost its "fair chance to litigate the Round 2 patents prior to actual marketing." (*See id.* at 18.) And the federal district court would face a technologically intensive, hurried injunction motion, what Judge Taranto described as the "reliability-reducing rush." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063 (Fed. Cir. 2016), *cert. denied*, 580 U.S. __ (Dec. 12, 2016).

B. This Court Should Permit BPCIA Case Law To Develop Further in the Lower Courts

In addition to confirming the flaws in Sandoz's attack on the Federal Circuit's construction of subparagraph 262(*l*)(8)(A), the Government's brief also confirms the wisdom of denying Sandoz's petition to allow these issues to percolate further in the lower courts.

Various inconsistencies and logical leaps in the Government's brief likewise highlight how early this case arises and the dangers of this Court adjudicating one portion of the statute before additional cases flesh out other provisions of the BPCIA. For example:

• The Government assumes that preliminary-injunctive relief during the 180-day notice period is "expressly limited to claims involving" the "Round 2" patents. (U.S. Br. 17.) The text of the statute does not support this. Nothing in subparagraph 262(*l*)(8)(A) limits the availability of injunctive relief to certain patents. Subparagraph 262(*l*)(8)(B) discusses those "Round 2" patents, but says nothing about being limited to them. No lower court has yet addressed this issue.

• The Government inconsistently suggests that submitting an aBLA is an act of infringement, while at other times suggesting that the Applicant's subsequent failure to provide the aBLA to the Sponsor creates the act of infringement. (*Compare* U.S. Br. 3, 6, *with id.* at 4-5.) It seems clear from the statute that submission of the aBLA is the technical act of infringement, but the lower courts

should be permitted to develop and clarify this area of law before the Court addresses it.

• The Government equates suing for patent infringement with seeking a declaratory judgment, and it therefore reads the limitations on declaratory judgments in paragraph 262(*l*)(9) as limitations on infringement suits. (*See, e.g.*, U.S. Br. 8, 16.) As the Federal Circuit recognized in *Apotex*, however, a declaratory-judgment action is not the same thing as an infringement suit, and a declaratory-judgment action seems a particularly poor "remedy" for some of the "fail[ures]" described in paragraph 262(*l*)(9). *See Apotex*, 827 F.3d at 1065. Before the Court simply accepts that infringement suits and declaratory-judgment actions are one and the same, as the Government suggests, it should have the benefit of lower court opinions addressing these issues.

There will be ample opportunity for swift further development of the law. The Federal Circuit has already addressed subparagraph 262(*l*)(8)(A) in the wake of *Sandoz*, in the *Apotex* case. The Federal Circuit currently has another BPCIA case before it addressing *Sandoz* and the proposition that where an Applicant refuses to provide other "manufacturing information" with its aBLA, the Sponsor may file suit and "'access the required information through discovery.'" (U.S. Br. 11 (quoting Pet. App. 17a-18a).) *See Amgen Inc. v. Hospira, Inc.*, No. 16-2179 (Fed. Cir. appeal docketed June 7, 2016).

This Court should deny Sandoz's petition and allow these issues to percolate further in the lower courts.

II. THE GOVERNMENT'S BRIEF REINFORCES THAT THE COURT SHOULD GRANT AMGEN'S CONDITIONAL CROSS-PETITION IF IT GRANTS SANDOZ'S PETITION

The Government agrees that if the Court grants Sandoz's petition it should grant Amgen's conditional cross-petition as well. (U.S. Br. 1, 13, 24.) Subparagraphs 262(*l*)(2)(A) and 262(*l*)(8)(A) "are integrally related," and the "proper interpretation of those provisions has a significant impact on the operation of the BPCIA." (*Id.* at 13.)

The Government's arguments themselves underscore the need for the Court to consider these two provisions in tandem, if at all.

First, the Government entirely ignores the Federal Circuit's rationale for why subparagraphs 262(*l*)(2)(A) and (*l*)(8)(A) should be treated differently. This case presents two statutory provisions using the same verb, yet the Federal Circuit construed one "shall" as mandatory and one as not mandatory. It rested that distinction on language in the BPCIA that it construed as specifying the exclusive consequences for a failure to comply with the first provision, and the absence of parallel language addressing the second provision. The Government glosses over this. This Court's review of the Federal Circuit's construction of one provision would necessarily implicate the other, however. If one is considered, they should be reviewed together.

Second, the Government proposes a rule under which disclosure by the Applicant is not required under either provision: The Applicant cannot be compelled to provide its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A) or pre-marketing notice under subparagraph 262(*l*)(8)(A). If accepted, those positions would negate the balance that Congress sought to achieve in the BPCIA, and would impose intolerable burdens on Sponsors and federal district courts, promoting launch-at-risk tactics that imperil patient continuity of care, as described above. The Court should review both provisions together as part of a unitary disclosure scheme.

Third, under the Government's reading, a Sponsor may never be able to access information about the Applicant's manufacturing process. Without the aBLA and manufacturing information, the Sponsor would have to guess what patents to assert. And without 180 days' notice, the Sponsor would have to request, receive, digest, and sue on highly technical information in the compressed rush of a preliminary-injunction motion. Details will get missed. Valid claims will go unasserted. And Sponsors may never be able to assert manufacturing patents. This consequence, too, compels review of both provisions together if the Court reviews either.

CONCLUSION

The Court should deny Sandoz's petition. If the Court grants that petition, it should also grant Amgen's conditional cross-petition.

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DECEMBER 20, 2016

RECORD AND BRIEFS

FILED
FEB 17 2017
OFFICE OF THE CLERK
SUPREME COURT, U.S.

Nos. 15-1039 and 15-1195

In the Supreme Court of the United States

SANDOZ INC., PETITIONER

v.

AMGEN INC., ET AL.

AMGEN INC., ET AL.,
CONDITIONAL CROSS-PETITIONERS

v.

SANDOZ INC.

ON WRITS OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER/CROSS-RESPONDENT

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QUESTIONS PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 804, establishes an abbreviated process for licensing "biosimilar" versions of licensed biological products (reference products). 42 U.S.C. 262(k). In conjunction with that process, the BPCIA establishes a series of steps for the resolution of potential patent claims by the sponsor of the reference product and the biosimilar applicant. § 262(*l*). Among other things, Subsection (*l*)(2)(A) of Section 262 provides that the applicant "shall provide to" the sponsor a copy of the biosimilar application and information about the product's manufacturing processes. Subsection (*l*)(8)(A) provides that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

1. The question presented in No. 15-1195 is whether Subsection (*l*)(2)(A) creates a binding disclosure obligation that a court may enforce by injunction, or whether the sponsor's sole recourse for the applicant's failure to disclose the information is the right, prescribed elsewhere in the BPCIA, to commence an immediate action for patent infringement.

2. The questions presented in No. 15-1039 are (a) whether notice of commercial marketing under Subsection (*l*)(8)(A) is legally effective if it is given before Food and Drug Administration (FDA) approval of the biosimilar application, and, if not, (b) whether Subsection (*l*)(8)(A) is a stand-alone requirement that may be enforced by means of an injunction that delays the marketing of the biosimilar until 180 days after FDA approval.

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In the Supreme Court of the United States

No. 15-1039

SANDOZ INC., PETITIONER

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ON WRITS OF CERTIORARI
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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER/CROSS-RESPONDENT

INTEREST OF THE UNITED STATES

Section 351 of the Public Health Service Act, 42 U.S.C. 262 (hereinafter Section 262), governs licensing of biological products and establishes a process for contemporaneously resolving certain related patent disputes. The Food and Drug Administration (FDA) administers that licensing process and implements related provisions. *E.g.*, 42 U.S.C. 262(a) and (k). The United States Patent and Trademark Office is responsible for issuing patents and, through the Secretary of

Commerce, advising the President on patent policy. 35 U.S.C. 2(a)(1) and (b)(8). At the Court's invitation, the United States filed a brief as amicus curiae at the petition stage of this case.

STATEMENT

1. This case concerns the framework in 42 U.S.C. 262(*l*) for facilitating the resolution of certain patent disputes that arise in connection with FDA licensing of "biological products" (also known as "biologics") under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 804.[1]

A "biological product" is "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein * * * , or analogous product * * * applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. 262(i)(1). Biologics may be "isolated from a variety of natural sources—human, animal, or microorganism"—and generally are more complex than drugs approved under 21 U.S.C. 355.[2]

a. Section 262 establishes two routes for biologic licensing. 42 U.S.C. 262(a)(1)(A). First, FDA may license a biologic under Section 262(a) if, *inter alia*, the biologic itself has been demonstrated to be "safe, pure, and potent." § 262(a)(2)(C)(i). Second, the BPCIA provides, in Section 262(k), an abbreviated licensing process generally analogous to the process for approv-

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[1] The BPCIA's primary provisions are codified at 28 U.S.C. 2201(b), 35 U.S.C. 271(e)(2)(C), (4)(B)-(D), and (6), and 42 U.S.C. 262(i) and (k)-(m).

[2] FDA, *What Are "Biologics" Questions and Answers* (2015), http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm.

ing generic drugs under the Hatch-Waxman Amendments, 21 U.S.C. 355(j). Under Section 262(k), FDA may approve an abbreviated biologic license application (aBLA) if, *inter alia*, the biologic at issue is shown to be "biosimilar" to a previously approved biologic (*i.e.*, the "reference product"). 42 U.S.C. 262(k)(3)(A); see § 262(i)(2) and (4). Developing a biosimilar is substantially more time-consuming and expensive than developing a generic drug, with estimates ranging from approximately eight to ten years and $100-$200 million for development.[3] In addition, establishing commercial manufacturing facilities for biological products can cost $250 million to $1 billion.[4]

An applicant seeking a license for a biologic may pursue either of the two routes above. But if it elects to submit an aBLA, the BPCIA prohibits its submission earlier than four years after FDA first licensed the reference product and prohibits FDA from making its approval effective earlier than 12 years after that first licensing of the reference product. 42 U.S.C. 262(k)(7)(A) and (B).

b. A reference product may be protected by various patents, including product (*e.g.*, composition) patents, method-of-use patents, and manufacturing-process patents. But without the BPCIA's special patent-dispute-resolution provisions, patent litigation, including issues of patent invalidity, would have faced obstacles if filed *before* a biosimilar is licensed and

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[3] Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* 14 (June 2009), https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

[4] *Ibid.*

marketed, for two primary reasons. First, it is not an act of patent infringement "to make, use, offer to sell, or sell * * * a patented invention" (other than a new animal drug or veterinary biological product) "solely for uses reasonably related to the development and submission of information," 35 U.S.C. 271(e)(1), while seeking approval for, *inter alia*, a "human biological product[]." *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 665, 674 (1990); see *id.* at 668-669. Second, anticipatory infringement claims would have had to overcome ripeness concerns if litigated before FDA approval and actual commercial marketing of a biosimilar. Cf. § 271(a) (infringement includes "mak[ing], us[ing], offer[ing] to sell, or sell[ing] any patented invention").

i. The BPCIA facilitates early resolution of patent claims by establishing a so-called "artificial" patent-infringement claim that may be litigated while FDA reviews an aBLA. Cf. *Eli Lilly & Co.*, 496 U.S. at 675-678 (discussing "artificial" infringement in generic-drug context). A generally applicable Patent Act provision provides private parties with a "civil action for [patent] infringement." 35 U.S.C. 281. In two specific situations discussed below, the BPCIA makes it "an act of infringement [with respect to specified categories of patents] to submit" an "application seeking approval of a biological product" if the "purpose of such submission is to obtain approval * * * to engage in the commercial manufacture, use, or sale of a * * * biological product claimed in a patent or the use of which is claimed in a patent" before that patent expires. § 271(e)(2)(C).

ii. Section 262(*l*), in turn, establishes a four-phase process for resolving patent disputes in litigation be-

tween the aBLA applicant (applicant) and the reference-product sponsor (sponsor). See 42 U.S.C. 262(*l*)(2)-(9). This brief refers to those phases as the

(1) Information Phase, § 262(*l*)(2);
(2) Comprehensive List Phase, § 262(*l*)(3);
(3) Round 1 Litigation Phase, § 262(*l*)(4)-(6); and
(4) Round 2 Litigation Phase, § 262(*l*)(8) and (9)(A).

The BPCIA further provides detailed consequences for failing to follow Section 262(*l*)'s patent-dispute-resolution process. See 35 U.S.C. 271(e)(2)(C) and (6); 42 U.S.C. 262(*l*)(9)(B) and (C). Those consequences, as explained below, can accelerate the timing, and modify the scope, of the ensuing patent litigation.

First, in the Information Phase, the applicant "shall provide to the * * * sponsor," within 20 days of FDA's acceptance of its aBLA for review, both a copy of the aBLA and manufacturing-process information. 42 U.S.C. 262(*l*)(2)(A). The sponsor's "confidential access" to that "information required to be produced pursuant to [Section 262(*l*)](2)" is for the "sole and exclusive purpose" of allowing the sponsor to determine "whether a claim of patent infringement could reasonably be asserted if the [applicant] engaged in the manufacture, use, offering for sale, sale, or importation" of its biosimilar. § 262(*l*)(1)(B)(i) and (D); see § 262(*l*)(1)(H) (authorizing "immediate injunctive relief" for improper disclosure).

If the applicant, however, "fails to provide the application and information required under [S]ection [262](*l*)(2)(A)," the applicant's submission of its aBLA is deemed an (artificial) "act of infringement" with respect to "a patent that could be identified pursuant to [S]ection [262](*l*)(3)(A)(i)" by the sponsor in the Comprehensive List Phase, discussed below. 35 U.S.C.

271(e)(2)(C)(ii). The sponsor may then file a patent-infringement action under the private right of action in 35 U.S.C. 281. Also, due to the applicant's "fail[ure] to provide" the "information required under [Section 262(*l*)](2)(A)," the "sponsor, but not the * * * applicant," may bring a declaratory-judgment action based on "any patent that claims the biological product or a use of the biological product." 42 U.S.C. 262(*l*)(9)(C). The question presented in No. 15-1195 concerns whether, in addition to those express statutory consequences, a court may enjoin the applicant to provide the Section 262(*l*)(2)(A) information to the sponsor.

Second, in the Comprehensive List Phase, the sponsor and applicant produce a list of patents on which (actual) patent-infringement claims could reasonably be asserted "if a person * * * engaged in the making, using, offering to sell, selling, or importing" of the biosimilar, 42 U.S.C. 262(*l*)(3)(A)(i) and (B)(i). See § 262(*l*)(3). Within 60 days of receiving the applicant's aBLA and manufacturing-process information, the sponsor "shall provide" to the applicant a list of such patents, § 262(*l*)(3)(A)(i), and identify which patents, if any, it would be prepared to license, § 262(*l*)(3)(A)(ii). If the sponsor fails timely to include "a patent that should have been included in the list," the sponsor cannot later assert any claim for "infringement of the patent with respect to the [applicant's biosimilar]." 35 U.S.C. 271(e)(6)(C).

Within 60 days after receipt of the sponsor's list, the applicant "may provide" the sponsor with its own list of patents on which "infringement [claims] could reasonably be asserted"; "shall provide" a response to each patent on the sponsor's list explaining why commercially marketing the biosimilar will not violate the

sponsor's patent rights; and "shall provide" a response to the sponsor's licensing offer. 42 U.S.C. 262(*l*)(3)(B). Within 60 days after receipt of the applicant's list, the sponsor then "shall provide" the applicant a detailed statement why the patents on the sponsor's list would be infringed and a response concerning the validity and enforceability of patents on the applicant's list. § 262(*l*)(3)(C).

The applicant's submission of its aBLA is deemed an (artificial) act of infringement "with respect to a patent that is identified in the list of patents described in [S]ection [262](*l*)(3)," *i.e.*, in the Comprehensive List. 35 U.S.C. 271(e)(2)(C)(i). As discussed below, however, other BPCIA provisions control the timing and scope of infringement claims for patents identified on the Comprehensive List, which can proceed in two potentially overlapping rounds of litigation.

Third, in the Round 1 Litigation Phase, the applicant and sponsor identify patents for prompt (Round 1) infringement litigation. 42 U.S.C. 262(*l*)(4)-(6). If within 15 days they reach agreement on such a "list of * * * patents," the "sponsor shall bring an action for patent infringement with respect to each such patent" within 30 days. § 262(*l*)(4) and (6)(A).

If they do not reach agreement within 15 days, the applicant "shall notify" the sponsor of "the number of patents" that the applicant will designate for its Round 1 list; then within five days, the applicant and sponsor "shall simultaneously" exchange their Round 1 lists. 42 U.S.C. 262(*l*)(5)(A) and (B)(i). The "number of patents listed" by the sponsor for Round 1 litigation may not exceed the number listed by the applicant, but if the applicant lists no patents the sponsor may list one. § 262(*l*)(5)(B)(ii). The sponsor then "shall

bring an action for patent infringement" for each patent on the Round 1 lists within 30 days. § 262(*l*)(6)(B).

If the applicant and sponsor successfully complete the actions required of them in the Information, Comprehensive List, and Round 1 Litigation Phases, the sponsor's Round 1 artificial-infringement action will be filed no more than roughly 250 days after FDA accepts the applicant's aBLA for review. See 42 U.S.C. 262(*l*)(2)-(6). But if the sponsor fails to file the Round 1 litigation within the requisite 30-day period, or if its action for infringement of a patent on a Round 1 list is dismissed without prejudice or not prosecuted in good faith, the sponsor's "sole and exclusive" remedy for infringement of such a Round 1 patent is a "reasonable royalty." 35 U.S.C. 271(e)(6)(A) and (B).

Fourth, the Round 2 Litigation Phase covers the remaining patents on the Comprehensive List not included on the Round 1 list. Cf. 42 U.S.C. 262(*l*)(8)(B)(i) and (ii) (remaining patents). The BPCIA normally postpones litigation on the Round 2 patents. Specifically, if the applicant timely provided the sponsor with the information required in Subsection (*l*)(2)'s Information Phase, neither the sponsor nor the applicant may bring a declaratory-judgment action based on a Round 2 patent before the applicant provides advance notice of the first commercial marketing of its biosimilar. § 262(*l*)(9)(A).

Section 262(*l*)(8)(A) governs the timing of that notice. It provides that the "applicant shall provide notice" to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [Section 262](k)." 42 U.S.C. 262(*l*)(8)(A). The questions presented in No. 15-1039 concern whether that notice may be given

before FDA approval of the biosimilar and, if not, whether a court may enjoin the applicant's marketing of its biosimilar for 180 days after FDA approval.

When such notice is given, the bar preventing the sponsor and applicant from bringing a declaratory-judgment action concerning the infringement, validity, or enforcement of a Round 2 patent is lifted. 42 U.S.C. 262(*l*)(9)(A). Moreover, "[a]fter receiving the notice * * * and before * * * the [biosimilar's] first commercial marketing," the "sponsor may seek a preliminary injunction" to enjoin the biosimilar's commercial manufacture or sale "until the court decides the issue of patent validity, enforcement, and infringement with respect to any [Round 2] patent." § 262(*l*)(8)(B).

Alternatively, even before any notice is given under Section 262(*l*)(8)(A), the "sponsor, but not the * * * applicant," may bring a declaratory-judgment action concerning any patent on the sponsor's Comprehensive List (including any relevant Round 2 patent) if the applicant "fails" to complete significant steps in the Section 262(*l*) process—specifically, if the applicant fails to provide the sponsor with its timely explanation why marketing the biosimilar would not violate the sponsor's rights under patents on the sponsor's list (42 U.S.C. 262(*l*)(3)(B)(ii)); to provide the sponsor timely notice of the applicant's number of Round 1 patents or its Round 1 list (§ 262(*l*)(5)); to provide the Secretary of Health and Human Services with a timely copy of a complaint in the Round 1 litigation (§ 262(*l*)(6)(C)(i)); or to provide the sponsor the 180-day advance notice of the biosimilar's first commercial marketing (§ 262(*l*)(8)(A)). See § 262(*l*)(9)(B).

2. Since 1991, respondents/cross-petitioners (respondents) have marketed filgrastim under the brand name Neupogen. Pet. App. 8a. In May 2014, petitioner/cross-respondent (petitioner) submitted an aBLA seeking FDA approval of a biosimilar filgrastim product (with the trade name Zarxio) that listed Neupogen as its reference product. *Id.* at 8a-9a. On July 7, 2014, FDA notified petitioner that it had accepted the aBLA for review. *Id.* at 8a.

On July 8, 2014, petitioner notified respondents of the filing of petitioner's aBLA and stated petitioner's intent to launch its biosimilar immediately upon FDA approval, which it expected in "Q1/2 of 2015." Pet. App. 8a. Petitioner, however, elected not to provide respondents with a copy of its aBLA or manufacturing-process information under Section 262(*l*)(2)(A). *Ibid.* Petitioner informed respondents that respondents were therefore entitled to sue petitioner for patent infringement. *Ibid.*

3. In October 2014, respondents filed a district court action against petitioner, asserting, as relevant here, an (artificial) infringement claim based on a patent claiming a method of using filgrastim and a state-law unfair competition law (UCL) claim. Pet. App. 9a. Respondents' UCL claim rested on two alleged BPCIA violations: petitioner's failure to disclose information required by Section 262(*l*)(2)(A), and its allegedly ineffective advance notice of commercial marketing under Section 262(*l*)(8)(A). *Ibid.* Petitioner counterclaimed for a declaratory judgment on both BPCIA questions and on its contentions that respondents' patent was invalid and not infringed. *Ibid.* Respondents sought a preliminary injunction based on the state-law claims to prevent petitioner from mar-

keting its biosimilar. *Id.* at 10a, 58a. Respondents subsequently obtained petitioner's aBLA in discovery. *Id.* at 10a.

Later, on March 6, 2015, FDA approved petitioner's aBLA for all approved uses of Neupogen. Pet. App. 8a-9a. That same day, petitioner gave respondents a second notice of commercial marketing. *Ibid.*

Shortly thereafter, the district court denied injunctive relief and granted petitioner partial judgment on the pleadings. Pet. App. 56a-84a. The court concluded that petitioner permissibly declined to provide its aBLA and manufacturing-process information under Section 262(*l*)(2)(A), *id.* at 68a-73a, and permissibly gave notice under Section 262(*l*)(8)(A) before FDA approved its aBLA, *id.* at 73a-76a. The court rejected respondents' UCL claim on those federal-law grounds. *Id.* at 77a-78a. The court subsequently entered a Rule 54(b) partial final judgment. *Id.* at 11a.

4. The Federal Circuit granted an injunction pending appeal that prohibited petitioner from marketing Zarxio, Pet. App. 31a, and subsequently affirmed in part, vacated in part, and remanded. *Id.* at 1a-55a.

a. The court of appeals first concluded that petitioner could elect not to disclose its aBLA and manufacturing information under Section 262(*l*)(2)(A), subject only to the patent-litigation consequences specified in the BPCIA. Pet. App. 12a-18a. Although Section 262(*l*)(2)(A) states that the applicant "shall" provide that information, the court concluded that the statutory text must be understood in its broader statutory context. *Id.* at 14a-15a. Other BPCIA provisions in 35 U.S.C. 271(e)(2)(C)(ii) and 42 U.S.C. 262(*l*)(9)(C), the court explained, "explicitly contemplate[]" that the applicant might not provide that in-

formation and "specifically set[] forth the consequence for such failure: the [sponsor] may bring an infringement action," and the applicant is prohibited from bringing its own declaratory-judgment "action on patents that claim the biological product or its use." Pet. App. 15a-17a. Because the BPCIA does not "specify any non-patent-based remedies" for such a failure, the court concluded that the sponsor's only recourse is to pursue its patent-infringement action, in which the sponsor can then "access the required information through discovery." *Id.* at 17a-18a. Judge Newman dissented from that holding. *Id.* at 32a-42a.

b. The court of appeals concluded, however, that an aBLA applicant must give its advance notice of first commercial marketing under Section 262(*l*)(8)(A) *after* FDA approves its aBLA. Pet. App. 18a-26a. The court reasoned that the requirement to give notice 180 days before the first commercial marketing of the applicant's "biological product licensed under [Section 262](k)," 42 U.S.C. 262(*l*)(8)(A), contemplates that the biosimilar must be "licensed" before notice is given. Pet. App. 20a-21a. The court then "extended" its injunction enjoining the marketing of Zarxio until September 2, 2015, *i.e.*, 180 days after petitioner gave its second notice to respondents. *Id.* at 27a-28a, 31a.

Judge Chen dissented from that grant of injunctive relief. Pet. App. 42a-55a. He concluded that petitioner had no obligation to provide notice because Section 262(*l*)(8)(A) is not a "standalone provision," but rather is part of "the integrated litigation management process contemplated in (*l*)(2)-(*l*)(7)," and when, as here, the "applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Id.* at 43a.

c. The court of appeals affirmed the dismissal of respondents' UCL claim alleging a Section 262(*l*)(2)(A) violation, Pet. App. 26a-27a, and deemed respondents' UCL claim based on Section 262(*l*)(8)(A) to be moot in light of the court's extension of its injunction, *id.* at 27a-28a.

SUMMARY OF ARGUMENT

I. The Federal Circuit correctly held that, where an applicant fails at the outset to provide the sponsor with its aBLA and manufacturing-process information under Section 262(*l*)(2)(A), the sponsor's only recourse under the BPCIA is to bring an artificial-infringement action.

A. Section 262(*l*)(2)(A) states that the applicant "shall provide" specified information to the sponsor. That provision imposes a mandatory condition precedent for invoking Section 262(*l*)'s patent-dispute-resolution framework, but it does not address the consequences for failing to do so.

B. Congress specifically addressed those consequences in two other BPCIA provisions. First, Section 271(e)(2)(C)(ii) provides that, if an applicant fails to provide the Section 262(*l*)(2)(A) information, an artificial patent-infringement claim will arise with respect to a patent that the sponsor could have included on its Comprehensive List. 35 U.S.C. 271(e)(2)(C)(ii). The sponsor may then immediately bring suit under 35 U.S.C. 281 for patent infringement. Declaratory relief is the only relief available in such an action brought any significant amount of time before a biosimilar's commercial marketing. Second, if the applicant fails to provide the Section 262(*l*)(2)(A) information, Section 262(*l*)(9)(C) provides that the sponsor, but not the applicant, may bring an action for

declaratory relief on a product or method-of-use patent. Those express statutory consequences are exclusive.

C. Moreover, no cause of action exists for direct judicial enforcement of Section 262(*l*)(2)(A). Congress must itself create a cause of action for a litigant to enforce a federal statutory provision, yet respondents have never attempted to identify such a cause of action for their Section 262(*l*)(2)(A) claim. That omission is independently fatal to their position.

II. The Federal Circuit erred in holding that Section 262(*l*)(8)(A) requires an applicant to provide a 180-day advance notice of the first commercial marketing of its biosimilar *after* FDA licenses that biosimilar, and that a court may enjoin the applicant from such marketing until 180 days after such notice.

A. 1. Section 262(*l*)(8)(A) provides that the applicant shall provide notice to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [Section 262](k)." That text directly addresses the requisite timing by specifying the "late[st]" date "before" commercial marketing on which notice must be given. Nothing limits how early the applicant may give notice after FDA accepts its aBLA for review.

Section 262(*l*)(8)(A)'s single timing requirement reflects its function in the statutory framework. The applicant exercises substantial control over the scope of early Round 1 artificial-infringement litigation. Notice then lifts the statutory stay of artificial-infringement litigation based on the sponsor's remaining (Round 2) patents. By specifying that such notice be given at least 180 days before commercial marketing, Congress provided a reasonable period during

which the sponsor may litigate such Round 2 claims before commercial marketing. Consistent with that framework, the applicant can provide the sponsor even *more* time by giving notice earlier than necessary.

2. The Federal Circuit also erred in holding that notice is required even after the applicant declines to provide Section 262(*l*)(2)(A) information. Once the applicant has departed from Section 262(*l*)'s patent-dispute-resolution process, the sponsor may immediately bring an artificial-infringement claim for all relevant patents. As a result, the statutory function of notice—*i.e.*, to authorize litigation on Round 2 patents that the sponsor was prevented from pursuing—no longer applies.

B. In any event, injunctive relief is unavailable to enforce Section 262(*l*)(8)(A) for essentially the same reasons as it is to enforce Section 262(*l*)(2)(A): (1) The BPCIA's detailed provisions specify the exclusive consequence for failing to provide notice, *i.e.*, the sponsor may bring an artificial-infringement action for all relevant patents and, regardless, (2) no cause of action exists for judicial enforcement of the notice provision.

ARGUMENT

I. THE FEDERAL CIRCUIT CORRECTLY DENIED AN INJUNCTION TO COMPEL PETITIONER'S DISCLOSURE OF SECTION 262(*l*)(2)(A) INFORMATION

Section 262(*l*)(2)(A) provides that the applicant "shall provide" to the sponsor, within 20 days of FDA's acceptance of its aBLA, a copy of the aBLA and manufacturing-process information. 42 U.S.C. 262(*l*)(2)(A). The BPCIA further states that "if the applicant * * * fails to provide the application and information required under [S]ection [262](*l*)(2)(A),"

the applicant's "submi[ssion]" of its aBLA constitutes an artificial "act of infringement" for certain patents, 35 U.S.C. 271(e)(2)(C)(ii), on which the sponsor may bring a "civil action for [patent] infringement," 35 U.S.C. 281. The "sponsor, but not the * * * applicant," may then seek certain declaratory relief. 42 U.S.C. 262(*l*)(9)(C). The Federal Circuit correctly held that those express patent-litigation-focused consequences are exclusive when the applicant fails to furnish information under Section 262(*l*)(2)(A). Pet. App. 12a-18a.

A. Section 262(*l*)(2)(A) Does Not Address The Consequences Of An Applicant's Failure To Satisfy The Condition It Specifies

Respondents argue (Cross-Pet. 25-27) that Section 262(*l*)(2)(A)'s use of the term "shall" in providing that the applicant "shall provide" specified information—and related statutory references to information "required" to be produced—reflect that the Federal Circuit erred in concluding that the term "shall" in this context "does not mean 'must,'" Pet. App. 15a. The government agrees that the Federal Circuit misconceived the relevant inquiry in that respect. Section 262(*l*)(2)(A) is properly understood as imposing a mandatory condition precedent for invoking Subsection (*l*)'s specialized patent-dispute-resolution framework. The mandatory nature of that condition, however, does not suggest that a sponsor may obtain a court order to compel the furnishing of the information.

The Court unanimously held this Term that, even if a statute that specifies that an action "'shall' be [taken]" "creates a mandatory rule," the mandatory language "says nothing * * * about the remedy for a violation of that rule" and thus provides no "congres-

sional guidance" about what, if any, consequence should follow. *State Farm Fire & Cas. Co.* v. *United States ex rel. Rigsby*, 137 S. Ct. 436, 442 (2016). Instead, where a "statute does not specify" the "consequences" of violating a statutory procedure, this Court "look[s] to statutory language, to the relevant context, and to what they reveal about the purposes [the provision] is designed to serve." *Dolan* v. *United States*, 560 U.S. 605, 610 (2010). Here, however, the BPCIA, *does* specify the consequences for failing to provide information under Section 262(*l*)(2)(A). Those consequences are exclusive.

B. The BPCIA Elsewhere Specifies The Only Consequences For Not Providing Section 262(*l*)(2) Information

1. Two BPCIA provisions specifically address the consequences of an applicant's failure to provide the sponsor with its aBLA and manufacturing-process information "under [S]ection [262](*l*)(2)(A)." See 35 U.S.C. 271(e)(2)(C)(ii); 42 U.S.C. 262(*l*)(9)(C).

a. First, Section 271(e)(2)(C)(ii) provides that, when an applicant "fails to provide the application and information required under [S]ection [262](*l*)(2)(A)," the applicant's "submi[ssion]" of its aBLA is an "act of infringement" if the aBLA seeks "approval * * * to engage in the commercial manufacture, use, or sale of a * * * biological product" protected by an unexpired product or method-of-use patent. 35 U.S.C. 271(e)(2)(C)(ii) ("product [is] claimed in a patent or the use of which is claimed in a patent"). That infringement extends to any "patent that could be identified pursuant to [S]ection [262](*l*)(3)(A)(i)" by the

sponsor on a Comprehensive List. *Ibid.*[5] Those detailed provisions both specify the patents for litigation and utilize Section 281's pre-existing "private right of action for patent infringement," see *POM Wonderful LLC* v. *Coca-Cola Co.*, 134 S. Ct. 2228, 2240 (2014), to allow the sponsor immediately to bring suit for patent-focused relief.

In this way, Section 271(e)(2)(C) follows the path that Congress established earlier in the generic-drug context under Section 271(e)(2)(A), which allows a patent holder to bring "a declaratory judgment action" to litigate relevant patents by "creat[ing] an 'artificial' act of infringement" to "provide[] a jurisdictional basis for a declaratory judgment suit against a generic manufacturer." *Glaxo Grp. Ltd.* v. *Apotex, Inc.*, 376 F.3d 1339, 1344, 1351 (Fed. Cir. 2004). Such a declaratory judgment is a muscular tool: It provides a basis for both (1) prompt injunctive relief should actual infringement resulting from a later commercial launch become imminent, see 28 U.S.C. 2202 (authorizing supplemental relief "based on a declaratory judgment"), and (2) treble damages against an applicant who flouts the declaration by subsequently engaging in such (willful) infringement, cf. *Halo Elecs.*,

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[5] The infringement extends not only to product and method-of-use patents, but also to a manufacturing-process patent, when the patent could be asserted "if a person * * * engaged in the *making*, using, offering to sell, selling, or importing" of that biosimilar, 42 U.S.C. 262(*l*)(3)(A)(i) (emphasis added). That conclusion is confirmed by the fact that the applicant's provision of information on the "processes used to manufacture" its biosimilar, § 262(*l*)(2)(A), is "for the sole and exclusive purpose" of allowing the sponsor to determine if it could assert "a claim of patent infringement," § 262(*l*)(1)(D). See Pet. App. 16a n.3.

Inc. v. *Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1930, 1932-1934 (2016) (construing 35 U.S.C. 284).

b. Section 262(*l*)(9) separately imposes "[l]imitation[s] on declaratory judgment action[s]" in three subparagraphs that identify when the "sponsor" and "applicant" are prohibited from seeking declaratory relief. 42 U.S.C. 262(*l*)(9).[6] As relevant here, Section 262(*l*)(9)(C) provides that, "[i]f" the applicant "fails to provide the application and information required under [Section 262(*l*)](2)(A)," the "sponsor, but not the * * * applicant," may bring a declaratory-judgment action "for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." § 262(*l*)(9)(C).

2. Those express statutory consequences for an applicant's failure to provide Section 262(*l*)(2)(A) information are both logical and significant. The sole function of Section 262(*l*) is to establish patent-dispute-resolution procedures that control the timing and scope of patent-infringement litigation between the sponsor and applicant. See pp. 4-9, *supra*. A central "part of the [BPCIA's] design" is that, when the applicant chooses to invoke those dispute-resolution provisions, the BPCIA gives it significant "control" over "the scope of the [Round 1] litigation," *Amgen Inc.* v. *Apotex Inc.*, 827 F.3d 1052, 1062 & n.3

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[6] When an applicant brings a declaratory-judgment action as a "prospective defendant[]" to "establish [its] nonliability" on patent claims, *Beacon Theatres, Inc.* v. *Westover*, 359 U.S. 500, 504 (1959), "'federal patent law creates the cause of action'" because it reflects "the 'character of the threatened action'" that the sponsor would bring against the applicant. *Medtronic, Inc.* v. *Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 848 (2014) (citations omitted).

(Fed. Cir.), cert. denied, 137 S. Ct. 591 (2016), which the sponsor must promptly initiate (about 250 days or less) after FDA accepts an aBLA. See pp. 5-8, *supra*. The applicant, for instance, may restrict that litigation to just one patent or, conversely, expand it to include all relevant patents. See 42 U.S.C. 262(*l*)(5)(B)(i)(I), (ii)(II), and (6)(B). But if the applicant declines to give timely Section 262(*l*)(2)(A) information to the sponsor, the applicant forfeits that control and the BPCIA vests the sponsor with the option of immediately bringing an (artificial) infringement action with respect to *all* relevant patents at a time of its own choosing. See pp. 17-18 & n.5, *supra*.

Where, as here, Congress has provided specific statutory consequences for failing to follow a statutory procedure, those consequences are properly deemed exclusive. The BPCIA's "carefully crafted and detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly." *Great-West Life & Annuity Ins. Co.* v. *Knudson*, 534 U.S. 204, 209 (2002) (citation and internal quotation marks omitted).

C. No Cause Of Action Exists To Compel Disclosure Of Section 262(*l*)(2)(A) Information

The court of appeals' judgment was correct for a second reason: No cause of action exists for independent enforcement of Section 262(*l*)(2)(A).

A plaintiff must possess a private "'cause of action'" in order to "judicially enforce the statutory rights or obligations" it seeks to vindicate. *Davis* v. *Passman*, 442 U.S. 228, 239 (1979); see *Touche Ross & Co.* v. *Redington*, 442 U.S. 560, 568 (1979) ("[T]he fact that a federal statute has been violated and some

person harmed does not automatically give rise to a private cause of action in favor of that person.") (citation omitted). Whether a "cause of action" exists to "enforce the right at issue" is a question "analytically distinct" from both the court's constitutional or statutory jurisdiction to hear the cause and the "question of what relief, if any, a litigant may be entitled to receive." *Davis*, 442 U.S. at 239 & n.18.

This Court has made clear that a "private right[] of action to enforce federal law must be created by Congress." *Alexander* v. *Sandoval*, 532 U.S. 275, 286 (2001). "[C]ourts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-287. "[A]n implied cause of action" is recognized "only if the underlying statute can be interpreted to disclose [Congress's] intent to create one." *Stoneridge Inv. Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008). And recognizing a cause of action based on inferred, rather than express, intent is a decidedly "rare step." *Paroline* v. *United States*, 134 S. Ct. 1710, 1725 (2014). Even before the Court's more recent decisions significantly narrowed the circumstances under which a private right of action may be inferred, the Court was "extremely reluctant to imply a cause of action * * * that is significantly broader than" an "express civil remedy" that "Congress [has] chose[n] to provide." *Touche Ross & Co.*, 442 U.S. at 574.

The BPCIA, as noted, specifically addresses the consequences of failing to provide Section 262(*l*)(2)(A) information, by making the "*submi*[*ssion*]" of an aBLA an artificial "act of infringement," 35 U.S.C. 271(e)(2)(C)(ii) (emphasis added), actionable under

Section 281's express cause of action for patent-infringement. See pp. 17-18, *supra*. Section 281, however, provides no basis for an action to compel an applicant to supply information under Section 262(*l*)(2)(A) because, as respondents concede, "[f]ailing to provide [such information] is *not* an act of infringement." Cross-Pet. 37. Respondents have never attempted to identify any cause of action permitting a sponsor to seek such an order. That omission is independently fatal to their claim to an injunction based on Section 262(*l*)(2)(A).

D. Respondents' Contrary Arguments Are Misplaced

Respondents' various certiorari-stage arguments reflect a misunderstanding of the BPCIA and relevant governing principles.

1. Respondents argue (Supp. Cert. Br. 11), for instance, that "a declaratory-judgment action is not the same thing as an infringement suit" and that declaratory relief is a "poor 'remedy'" for not providing Section 262(*l*)(2)(A) information. That apparently is so, in respondents' view (Cross-Pet. 34), because a sponsor cannot obtain declaratory relief on a manufacturing-process patent. Congress, however, must be taken to have determined the adequacy of the specific consequences it enacted for failing to provide that information. Moreover, respondents fundamentally misapprehend the statutory scheme.

Section 281 is the only cause of action available on which a sponsor may seek declaratory relief for an (artificial) act of infringement as defined by Section 271(e)(2)(C), and such declaratory relief extends to manufacturing-process patents. See pp. 17-18 & n.5, *supra*. No other provision provides the requisite cause of action. Although Section 262(*l*)(9)(C) cites

the Declaratory Judgment Act, 28 U.S.C. 2201 *et seq.*, that Act "presupposes the existence of a judicially remediable right," *Schilling* v. *Rogers*, 363 U.S. 666, 677 (1960), and merely "enlarge[s] the range of remedies available" with respect to an independent cause of action, *Skelly Oil Co.* v. *Phillips Petroleum Co.*, 339 U.S. 667, 671-672 (1950); *Wilton* v. *Seven Falls Co.*, 515 U.S. 277, 288 (1995). See *Ali* v. *Rumsfeld*, 649 F.3d 762, 778 (D.C. Cir. 2011) (Section 2201 does not "provide a cause of action.").

Moreover, declaratory relief is the only form of relief available in artificial-infringement actions at relevant times.[7] Although Section 271(e)(4) authorizes certain monetary and injunctive relief in such actions, 35 U.S.C. 271(e)(4)(B)-(D), a sponsor cannot bring an artificial-infringement action for such relief any significant amount of time before a biosimilar's commercial marketing. Monetary relief is available "only if there has [already] been commercial manufacture, use, offer to sell, or sale * * * or importation" of the biosimilar. § 271(e)(4)(C). A permanent injunction to "prohibit[] any infringement of [a] patent by the biological product" is available in certain circumstances, but only after "the patent is subject to a final court decision" in a Round 1 patent-infringement action,

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[7] The general unavailability of non-declaratory relief is critical to Section 262(*l*)'s patent-dispute-resolution framework. Section 262(*l*)(9) controls the timing and scope of artificial-infringement actions by limiting certain "action[s] under [S]ection 2201 of [T]itle 28 for a declaration of infringement, validity, or enforceability." 42 U.S.C. 262(*l*)(9)(A)-(C). If a sponsor could simply pursue an artificial-infringement action for only *non*-declaratory relief—an action that Section 262(*l*)(9) does not expressly limit—the sponsor could bypass Section 262(*l*)'s detailed patent-dispute-resolution procedures.

§ 271(e)(4)(D), "from which no appeal * * * has been or can be taken," 42 U.S.C. 262(k)(6). That supplemental remedy after a final judgment that grants other relief is not a basis for filing the action in the first instance. Finally, a court may issue an injunction "to prevent the commercial manufacture, use, offer to sell, or sale * * * or importation" of an approved biosimilar, 35 U.S.C. 271(e)(4)(B), but such traditional equitable relief would be available only when such harms are sufficiently real and imminent.[8] Indeed, if a sponsor could establish the imminent commercial launch of a competitor's biosimilar, it would have no need for an *artificial*-infringement claim and could simply bring an action for actual patent infringement under 35 U.S.C. 271(a).[9]

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[8] See *eBay Inc.* v. *MercExchange, LLC*, 547 U.S. 388, 391-392, 394 (2006) (patent injunction based on actual infringement still requires proof of traditional equitable factors, including that plaintiff "has suffered an irreparable injury"); *City of L.A.* v. *Lyons*, 461 U.S. 95, 111 (1983) ("irreparable injury" warranting permanent injunction requires actual or sufficiently "immediate irreparable injury") (citation omitted); cf. Resp. Supp. Cert. Br. 8 (agreeing that injunction is unwarranted before FDA approval because no "imminent need for judicial action" yet exists).

[9] Courts may grant broader coercive monetary and injunctive relief in actions for *actual* patent infringement. See 35 U.S.C. 283-284. When Congress created artificial-infringement claims for generic drugs under the Hatch-Waxman Amendments in 1984, it clarified that the more limited monetary and injunctive remedies in Section 271(e)(4) were the "only remedies" for artificial infringement, other than an award of "attorney fees under [S]ection 285." 35 U.S.C. 271(e)(4); cf. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 678-679 (1990) (describing Section 271(e)(4) as defining "artificial" consequences for "artificial" infringement under an Act that is not an "elegant piece of statutory draftsmanship"). That comparative reference to the normal coercive patent reme-

2. Respondents argue that two purposes are served by continuing Section 262(*l*)'s patent-dispute-resolution process even *after* Section 271(e)(2)(C)(ii) has authorized the sponsor to file an immediate artificial-infringement action on *all* relevant patents. Neither withstands scrutiny.

a. Respondents contend (Cross-Pet. 28) that sponsors would "have no way of knowing" whether any manufacturing-process patents are implicated without the Section 262(*l*)(2)(A) information. That is incorrect. An artificial-infringement claim cannot rest on a manufacturing-process patent alone: Artificial infringement occurs only if the biosimilar itself or one of its uses is claimed in a patent. 35 U.S.C. 271(e)(2); see p. 17, *supra*. And as the Federal Circuit concluded, if a sponsor can file suit on such an artificial-infringement claim, it can obtain discovery into the applicant's manufacturing processes to determine the scope of the artificial infringement. Pet. App. 17a; cf. 35 U.S.C. 295.

b. Respondents also contend (Cross-Pet. 29-30) that if an applicant's failure to provide Section 262(*l*)(2)(A) information ends the Section 262(*l*) process, then Round 1 litigation under Section 262(*l*)(6) will not commence, thereby depriving the sponsor of the final judgment in such litigation that Section 271(e)(4)(D) requires before a sponsor obtains a man-

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dies in Sections 283-285, however, does not also limit declaratory relief for artificial-infringement claims. Such claims were properly understood to give rise to declaratory-judgment actions before Congress enacted the BPCIA, see p. 18, *supra*, and the BPCIA specifically amended the Declaratory Judgment Act to state that 42 U.S.C. 262 ("[S]ection 351 of the Public Health Service Act")—not Section 271(e)(4)—imposes "limitations on actions" for declaratory relief. 28 U.S.C. 2201(b); cf. 42 U.S.C. 262(*l*)(9) (limitations).

datory "permanent injunction prohibiting any infringement of [a] patent by the biological product," 35 U.S.C. 271(e)(4)(D). Assuming *arguendo* that respondents are correct that a court lacks equitable discretion to deny relief under Section 271(e)(4)(D), such a mandatory injunction is logically limited just to Round 1 cases.

The applicant largely controls the scope of Round 1 litigation and can effectively constrain the sponsor's ability to pursue its patent claims in that early lawsuit. See pp. 19-20, *supra*. If a sponsor prevails by obtaining a final and non-appealable judgment in Round 1 litigation notwithstanding the applicant's advantage of control, a mandatory post-judgment injunction serves to counterbalance the limited nature of the proceeding. But where, as here, the sponsor may immediately bring an artificial-infringement action on *all* relevant patents because the applicant has forfeited its control, no such compensation is warranted. The sponsor can pursue all of its patents and, if it prevails, will obtain fully adequate declaratory relief, with the possibility of injunctive relief should actual infringement later become imminent. See p. 18, *supra*.

II. THE FEDERAL CIRCUIT ERRED IN ISSUING AN INJUNCTION TO ENFORCE SECTION 262(*l*)(8)(A)

Section 262(*l*)(8)(A) provides that the "applicant shall provide notice" to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [Section 262](k)." 42 U.S.C. 262(*l*)(8)(A). That provision permits an applicant to give the sponsor its 180-day advance notice before FDA approves the aBLA. In any event, no cause of action exists under which respond-

ents could obtain injunctive relief to enforce Section 262(*l*)(8)(A)'s notice requirement.

A. Section 262(*l*)(8)(A) Allows Notice Of First Commercial Marketing Before FDA Approval

1. Notice need only be given "not later" than 180 days "before" commercial marketing

a. The text and purpose of Section 262(*l*)(8)(A)'s notice provision and the BPCIA's broader statutory context show that an applicant may give advance notice of the first commercial marketing of its biosimilar before FDA licenses that biosimilar.

First, Section 262(*l*)(8)(A)'s text directly addresses the question of timing: Notice must be given "*not later than* 180 days *before* the date of the first commercial marketing." 42 U.S.C. 262(*l*)(8)(A) (emphasis added). That language identifies the latest date by which notice must be given, thus allowing an applicant to provide notice *before* that date.

Section 262(*l*)(8)(A) includes no language imposing a front-end restriction limiting how soon the applicant may provide notice after FDA accepts its aBLA. By contrast, when Congress intended in the BPCIA to specify both the earliest and latest dates on which an action could occur, it did so expressly: The very next sentence of Section 262(*l*)(8) specifies that a sponsor may seek a preliminary injunction to enjoin such marketing "[*a*]*fter* receiving the notice * * * *and before* [the] date of the first commercial marketing," 42 U.S.C. 262(*l*)(8)(B) (emphasis added).

Second, requiring notice "not later than 180 days before" commercial marketing reflects the function that Section 262(*l*)(8)(A) plays in Section 262(*l*)'s patent-dispute-resolution framework. If an applicant

follows Section 262(*l*)'s procedures, the BPCIA gives it significant control over the scope of the early Round 1 artificial patent-infringement litigation under Section 262(*l*)(6). The applicant can restrict that litigation to a single patent, see p. 20, *supra*, and neither party may seek a declaratory judgment regarding the remaining (Round 2) patents until "notice is received under [Section 262](8)(A)." 42 U.S.C. 262(*l*)(9)(A).[10]

By requiring the applicant to give notice "not later than 180 days before" the biosimilar's first commercial marketing, 42 U.S.C. 262(*l*)(8)(A), Congress provided a reasonable, 180-day period within which the sponsor may pursue an artificial-infringement action for all remaining patents before the biosimilar's commercial launch. The sponsor also "may seek a preliminary injunction" in that action to halt the biosimilar's impending commercial manufacture or sale "until the court decides the issue of patent validity, enforcement, and infringement with respect to any [Round 2] patent." § 262(*l*)(8)(B).

But where, as here, the applicant provides more than 180 days notice, the applicant has given the sponsor *more* time than that statutorily required. The permissibility of that earlier notice is consistent with Section 262(*l*)(8)(A) and its surrounding provisions, which facilitate early litigation of patent claims. By contrast, the Federal Circuit disregarded the patent-focused function of Section 262(*l*) by requiring the

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[10] The remaining patents are those "described in clauses (i) and (ii)" of Section 262(*l*)(8)(B), see 42 U.S.C. 262(*l*)(9)(A), that is, the patents that are "included in the [Comprehensive L]ist" under Section 262(*l*)(3), see § 262(*l*)(8)(B)(i), and "*not* included" on the "list of patents" for Round 1 litigation, see § 262(*l*)(8)(B)(ii) (emphasis added).

applicant to give 180-day advance notice *after* FDA approval. Pet. App. 20a. Such notice would delay commercial marketing of a biosimilar for 180 days after approval, even when the sponsor has *no other patents* that arguably should delay such marketing. That strange result has no patent-based justification and would simply delay the statute's otherwise prompt processes for resolving patent disputes between the applicant and sponsor.

b. i. The Federal Circuit inferred its requirement that notice be given after FDA approval from the phrase "the date of the first commercial marketing of the biological product licensed under [Section 262](k)," 42 U.S.C. 262(*l*)(8)(A). In the court's view, the word "licensed" indicates that notice "must be given only after the product is licensed." Pet. App. 20a-21a. But "licensed" there is most naturally read as describing the biological product as of "the *date* of [its] first commercial marketing," § 262(*l*)(8)(A) (emphasis added). The statute simply requires that notice be given "not later than 180 days before th[at] date," *ibid.*, a time at which the product may not yet be licensed. The phrase "*the* biological product licensed *under* [*Section 262*](*k*)," *ibid.* (emphasis added), thus serves the function of appropriately identifying the biosimilar whose commercial marketing triggers notice.

The Federal Circuit hypothesized that if Congress had intended Section 262(*l*)(8)(A) "to permit effective notice *before* the product is licensed," it would have used language focused on that situation by referring to the "'product that is the subject of' the application," as it did elsewhere in Section 262(*l*). Pet. App. 20a (emphasis added) (citations omitted). That suggestion ignores that Section 262(*l*)(8)(A)'s 180-day advance

notice can occur either *before* licensing *or* (when commercial marketing begins more than 180 days after FDA approval) *after* licensing. Indeed, Congress used the term "licensed" elsewhere in the BPCIA to describe biosimilars when addressing actions that can occur either before or after FDA approval. Section 262(k)(5)(C)—which concerns regulatory authority that FDA may exercise before "approving the application" or after, 21 U.S.C. 355-1(a)(1) and (2)(A)—specifies that FDA has this same authority for "biological products *licensed* under [Section 262(k)]" as for those "licensed under [Section 262](a)." See 42 U.S.C. 262(a)(2)(D) and (k)(5)(C) (emphasis added).

Moreover, Section 262(*l*)(8)(A)'s specific textual focus on the biosimilar at "the date" upon which its marketing occurs distinguishes it from the other provisions in Section 262(*l*)'s Information and Comprehensive List phases cited by the court of appeals (Pet. App. 20a), that, for instance, require an entity to state its *present* views about the patent-law implications of the future commercial marketing of the "product that is the subject of the subsection (k) application." See, *e.g.*, 42 U.S.C. 262(*l*)(3)(B)(ii)(I) and (C).

ii. The Federal Circuit found its reading preferable because, by requiring that notice be given "after FDA licensure," it ensured that the Round 2 litigation triggered by the notice would involve a "fully crystallized controversy" for "injunctive relief." Pet. App. 21a. That rationale misunderstands, and runs against Congress's policy judgments embodied in, Section 262(*l*).

First, notice allows the sponsor to seek *declaratory* relief on its Round 2 patents by bringing the *artificial* patent-infringement claim in Section 271(e)(2)(C). See 42 U.S.C. 262(*l*)(9)(A); pp. 9, 17-18, 23-24, *supra*. Such

claims for declaratory relief can be fully litigated years before FDA approval. When the parties follow the schedule in Section 262(*l*)(2)-(6), for instance, the same issues for the same patents (if selected for early litigation) can proceed in Round 1 litigation, which would commence no later than roughly 250 days after FDA accepts the aBLA for review. See pp. 5-8, *supra*. And because the aBLA may be submitted eight years before FDA could grant an effective license, § 262(k)(7)(A) and (B), the BPCIA allows such patent litigation more than seven years *before* licensing.

Second, although a sponsor "may seek a preliminary injunction" in a post-notice (Round 2) artificial-infringement action to prevent "commercial manufacture or sale" of the biosimilar, 42 U.S.C. 262(*l*)(8)(B), the BPCIA does not reflect that the sponsor must seek that injunctive relief before commercial manufacture or sale becomes a real and imminent irreparable injury. Preliminary relief is an "extraordinary and drastic remedy" warranted only upon a "clear showing," *Mazurek* v. *Armstrong*, 520 U.S. 968, 972 (1997) (per curiam) (emphasis and citation omitted), that the plaintiff "will suffer irreparable injury" without it. *Doran* v. *Salem Inn, Inc.*, 422 U.S. 922, 931 (1975); see also p. 24 & n.8, *supra* (discussing permanent injunction). The Section 262(*l*)(8)(A) notice thus simply allows the sponsor to litigate its artificial-infringement claims on Round 2 patents in an action for declaratory relief and to seek injunctive relief at an appropriate time in that action.

iii. Respondents argue (Br. in Opp. 19) that Section 262(*l*)(9)(A)—which forestalls a declaratory-judgment action for Round 2 patents if the applicant has provided the sponsor with its Section 262(*l*)(2)(A)

information—would be "meaningless" if the notice that lifts that bar could be given as soon as the aBLA is submitted. That is incorrect. Early notice lifts the litigation-focused prohibition in Section 262(*l*)(9)(A) and thus allows either party to file a declaratory-judgment action concerning a Round 2 patent, as it otherwise could have done absent the prohibition.

Respondents also rely on Section 262(k)(6), which addresses an exclusivity period for the first "interchangeable" biosimilar, *i.e.*, a biosimilar that meets additional requirements and may be substituted for its reference product without the prescribing health-care provider's intervention. 42 U.S.C. 262(i)(3). Respondents contend (Br. in Opp. 18-19) that provisions within Section 262(k)(6) "suggest" that commercial marketing should follow FDA approval by "six months," apparently to suggest that this six-month delay supports the similar (but slightly shorter) 180-day post-approval delay that the Federal Circuit imposed. Section 262(k)(6), however, addresses the timing of an FDA interchangeability "determination under [Section 262(k)](4)," § 262(k)(6), which is different from FDA's approval of the product as a biosimilar. As petitioner explains (Br. 36-38), the timing of FDA's approval of a biosimilar application does not necessarily speak to the timing of its separate interchangeability determination.

2. Notice is not required if the applicant declines to provide Section 262(l)(2)(A) information

The Federal Circuit further erred in concluding that an applicant must provide notice under Section 262(*l*)(8)(A) even if the applicant declined at the outset of the BPCIA's patent-dispute-resolution process to disclose its aBLA and manufacturing-process infor-

mation under Section 262(*l*)(2)(A). In the Federal Circuit's view, Section 262(*l*)(8)(A) is a "standalone" notice provision that broadly "allow[s] the [sponsor] a period of time to assess and act upon its patent rights" generally. Pet. App. 25a-26a. That is incorrect.

Notice under Section 262(*l*)(8)(A) serves a more narrowly focused purpose: It terminates the BPCIA's prohibition against an artificial-infringement declaratory-judgment action with respect to *only Round 2 patents*, 42 U.S.C. 262(*l*)(9)(A), and allows the sponsor to seek in that action preliminary injunctive relief pending resolution of its Round 2 patent claims, § 262(*l*)(8)(B). The 180-day advance notice provides a reasonable period to commence Round 2 litigation before commercial marketing. See p. 28, *supra*.

But where, as here, an applicant's failure to take actions specified by Section 262(*l*) allows the sponsor immediately to bring an artificial-infringement action regarding *all* relevant patents, thereby divesting the applicant of its ability to control the pace and scope of litigation, see pp. 17-20, *supra*, the BPCIA's special provisions for litigation of Round 2 patents in Section 262(*l*)(9)(A) and Section 262(*l*)(8)(B) lose their significance. Cf. Pet. App. 43a, 48a-49a (Chen, J., dissenting). In such circumstances, the notice under Section 262(*l*)(8)(A) that triggers those provisions would serve no ongoing statutory function.

B. Injunctive Relief Is Not Available To Compel Notice Under Section 262(*l*)(8)(A)

The Federal Circuit imposed an injunction to enforce its reading of Section 262(*l*)(8)(A)'s notice requirement. Pet. App. 31a. Although respondents state (Br. in Opp. 29-30) that the court had authority under Appellate Rule 8(a) to extend its "injunction

pending appeal," that rationale makes little sense because the court had *resolved* that appeal. The Federal Circuit itself has read its decision here as holding more generally that "an injunction [i]s proper to enforce" Section 262(*l*)(8)(A). *Amgen Inc.*, 827 F.3d at 1054, 1060-1061; see *id.* at 1063-1065. That holding is incorrect for essentially the same reasons that courts may not enjoin an applicant to provide information under Section 262(*l*)(2)(A).

1. First, the BPCIA's detailed provisions specify the exclusive consequences for failing to follow the requirements in Section 262(*l*), all but one of which modify the timing and scope of artificial-infringement litigation. See pp. 5-9, *supra*. Congress made "injunctive relief" available only for a violation of certain confidentiality rules, see 42 U.S.C. 262(*l*)(1)(H), an occurrence that does not halt the ongoing patent-dispute-resolution process. That express provision for non-patent-based injunctive relief reflects an intent to limit such relief to that one Section 262(*l*) context.

The Federal Circuit relied on the purported absence of any provision specifically imposing "consequence[s] for[] noncompliance with [Subsection] (*l*)(8)(A)" where, as here, the applicant also failed to provide the sponsor information at the outset under Subsection (*l*)(2)(A). Pet. App. 24a-25a. If an applicant fails to complete a subsequent step in Section 262(*l*)'s multi-step process after providing such information at the outset—including by failing to provide notice under "[Subsection (*l*)](8)(A)"—the statutory consequence is that the sponsor may bring an artificial-infringement action for all patents on its Comprehensive List. 42 U.S.C. 262(*l*)(9)(B). Although the Federal Circuit correctly noted that that consequence

applies only if the applicant initially provided the information required by Section 262(*l*)(2)(A), Pet. App. 25a, it failed to recognize that specifically identifying such a consequence for failing to give Section 262(*l*)(8)(A) notice is entirely unnecessary if the applicant failed at the outset to furnish the Section 262(*l*)(2)(A) information. In those circumstances, the BPCIA *already* provides that the sponsor may bring suit on any relevant patent following such a failure. 35 U.S.C. 271(e)(2)(C)(ii); see pp. 17-18 & n.5, *supra*.

2. Injunctive relief is also unavailable for an independent reason: No cause of action exists for a sponsor to seek judicial enforcement of Section 262(*l*)(8)(A). See pp. 20-22, *supra*. Respondents simply ignore this shortcoming.

3. Finally, respondents argue (Supp. Cert. Br. 9) that the 180-day-advance-notice provision would be "gutted" if it is not enforceable by injunction. They contend (*ibid.*) that, without an injunction, an applicant could supply the information required by Section 262(*l*)(2)(A) and later launch its biosimilar without notice, thus depriving the sponsor of a fair chance to litigate its Round 2 patents before commercial marketing. Respondent's policy concern cannot overcome Congress's provision of a specific consequence for that scenario, see 42 U.S.C. 262(*l*)(9)(B); does not justify inferring a cause of action to supplement the BPCIA's detailed statutory provisions; and, in any event, is misplaced.

Although 21 C.F.R. 601.51(b) constrains FDA from revealing the existence of an undisclosed aBLA, petitioner correctly explains (Br. 48-51) that a surprise-launch strategy would be infeasible given the amount of public information available by the time FDA ap-

proves a biosimilar. An applicant, moreover, would be quite unlikely to engage in a surprise launch in the face of a potentially viable patent claim, given the applicant's substantial and ongoing monetary investments in its biosimilar (see p. 3, *supra*), which would be put at significant risk by the monetary-damages and injunctive sanctions for actual (not artificial) patent infringement. See Pet. Br. 51. Finally, if an applicant were nevertheless to launch without notice, the district court could take any failure to give notice under Section 262(*l*)(8)(A) into account when exercising its equitable discretion to award preliminary injunctive relief while a sponsor's actual patent-infringement claims are being litigated.

CONCLUSION

The judgment of the court of appeals should be affirmed in part, reversed in part, and remanded.

Respectfully submitted.

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FEBRUARY 2017

APPENDIX

1. 28 U.S.C. 1338 provides in pertinent part:

Patents, plant variety protection, copyrights, mask works, designs, trademarks, and unfair competition

(a) The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights. For purposes of this subsection, the term "State" includes any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands.

* * * * *

2. The Declaratory Judgment Act, 28 U.S.C. 2201 *et seq.*, provides:

§ 2201. Creation of remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the United States, upon the

filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act.

§ 2202. Further relief

Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.

3. 35 U.S.C. 271 provides in pertinent part:

Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

* * * * *

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary

biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

* * * * *

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

* * * * *

(4) For an act of infringement described in paragraph (2)—

* * * * *

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

* * * * *

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(*l*)(4) of the Public Health Service Act or the lists of patents described in section 351(*l*)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(*l*)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(*l*)(3)(A) of the Public Health Service Act, including as provided under section 351(*l*)(7) of such Act for a biological product, but was not timely included in such list, may

not bring an action under this section for infringement of the patent with respect to the biological product.

* * * * *

4. 35 U.S.C. 281 provides:

Remedy for infringement of patent

A patentee shall have remedy by civil action for infringement of his patent.

5. 35 U.S.C. 283 provides:

Injunction

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

6. 35 U.S.C. 284 provides:

Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may

increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d).

The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

7. 35 U.S.C. 285 provides:

Attorney fees

The court in exceptional cases may award reasonable attorney fees to the prevailing party.

8. Section 351 of the Public Health Service Act, 42 U.S.C. 262, provides in pertinent part:

Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

* * * * *

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

* * * * *

(6) Exclusivity for first interchangeable biological product

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection

(*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

* * * * *

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to para-

graph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

* * * * *

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

* * * * *

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offer-

ing to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and

legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later

than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforce-

ability of any patent that claims the biological product or a use of the biological product.

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RECORD AND BRIEFS.

Supreme Court, U.S.
FILED
FEB 17 2017
OFFICE OF THE CLERK

No. 15-1039

In the Supreme Court of the United States

SANDOZ, INC.,
Petitioner,

v.

AMGEN, INC., ET AL.,
Respondents.

On Writ of Certiorari to the
U.S. Court of Appeals for the Federal Circuit

BRIEF FOR AARP, AARP FOUNDATION, CITIZENS AGAINST GOVERNMENT WASTE, THE UAW RETIREE MEDICAL BENEFITS TRUST, THE NATIONAL HEALTH LAW PROGRAM, AND THE COALITION TO PROTECT PATIENT CHOICE AS AMICI CURIAE IN SUPPORT OF PETITIONER SANDOZ, INC.

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INTERESTS OF AMICI CURIAE[1]

AARP is a nonprofit, nonpartisan organization dedicated to fulfilling the needs and representing the interests of people age fifty and older. AARP fights to protect older people's financial security, health, and well-being. AARP's charitable affiliate, AARP Foundation, creates and advances effective solutions that help low-income individuals fifty and older secure the essentials. Among other things, AARP and AARP Foundation advocate for prompt consumer access to lower-cost prescription drugs, including through participation as amici curiae in federal courts. *E.g.*, *Fed. Trade Comm'n v. Actavis*, 133 S. Ct. 2223 (2013); *N.Y. v. Actavis*, 787 F.3d 638 (2d Cir. 2015); *King Drug Co. of Florence v. SmithKline Beecham Corp*, 791 F.3d 388 (3d Cir. 2015).

Citizens Against Government Waste (CAGW) is a 501(c)(3) private, nonpartisan, nonprofit organization representing more than 1 million members and supporters nationwide. CAGW works to eliminate waste, fraud, abuse, and mismanagement in government through research and public education activities. Founded in 1984 by the late businessman J. Peter Grace and late Pulitzer Prize-winning columnist Jack Anderson, CAGW is the legacy of President Ronald Reagan's Private Sector Survey on Cost Control, also known as the

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[1] No counsel for a party authored this brief in whole or in part or made a monetary contribution to fund the preparation or submission of this brief. No persons other than amici, their members, or their counsel made such a monetary contribution. Counsel for the parties consented to the filing of this brief.

Grace Commission. CAGW believes that competition and market forces are the best solutions for creating greater access to pharmaceuticals, encouraging more innovation, and lowering healthcare costs.

The UAW Retiree Medical Benefits Trust ("Trust") provides health care benefits for retired UAW members of General Motors, Ford, and Chrysler, along with their eligible dependents. This arrangement was made possible through a provision in the 2007 collective bargaining agreements between the UAW and the three auto companies under which all of the retiree health care liabilities were transferred to a new independent Voluntary Employee Beneficiary Association (VEBA). The Trust currently provides health care benefits to 703,807 persons. In addition to hospital and medical benefits, the Trust also provides prescription drug coverage to its enrollees. Nearly half of the Trust's annual expenditures are for prescription drug coverage. Many of the Trust's enrollees have complex medical needs and require specialty medications. As a result, biologic medical products are one of the fastest growing prescription drug costs for the Trust. Accordingly, the introduction and advancement of biologic medical products are important to the health and well-being of our enrollees. The Trust and its enrollees therefore have a significant interest in the rapid entry of lower cost biosimilar productions.

The National Health Law Program (NHeLP) is a 40-year old public interest law organization that engages in education, litigation, and policy analysis

to advance access to quality health care and protect the legal rights of low income people, people with disabilities, older adults, and other underserved populations. NHeLP works to help individuals and their advocates overcome barriers to health care, including access to necessary and affordable prescription drugs.

The Coalition to Protect Patient Choice (CPPC) is a non-incorporated coalition representing consumer interests united to protect patient choice in all healthcare markets. The CPPC advocates to protect consumers' ability to access quality healthcare, affordable health insurance, and lower-cost prescription drugs.

Amici submit this brief because the Federal Circuit misinterpreted the Biologics Price Competition and Innovation Act (BPCIA) to require an additional period of market exclusivity for biologics manufacturers beyond the twelve years already contemplated in the statute. The cost of any additional period of market exclusivity for prescription drugs is ultimately borne by consumers and taxpayers generally, and by older adults in particular. Amici do not address the issues raised in the cross-petition filed by Amgen. *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), *cert. granted*, 85 U.S.L.W. 3343 (U.S. Jan. 13, 2017) (No. 15-1195).

SUMMARY OF ARGUMENT

Respondent Amgen manufactures Neupogen, a biologic drug commonly used to stimulate the body's production of white blood cells in patients undergoing chemotherapy. Amgen, Inc., *About Neupogen*, http://www.neupogen.com/about/ (*last accessed* Feb. 13, 2017). Approved by the Food and Drug Administration (FDA) in March 2015, Petitioner Sandoz's product Zarxio was the first biosimilar drug approved under the new pathway for licensing of biosimilars under the BPCIA. Generics and Biosimilars Initiative, *Biosimilars Approved in the U.S.* (*last updated* Sept. 30, 2016), http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-the-US. As such, this case represents a critical juncture in the BPCIA's compromise between encouraging innovation and controlling costs of biologic drugs.

Biologic drugs represent a large and growing segment of the overall prescription drug market. Older adults, who as a group often require more daily prescription drugs and shoulder a higher share of the overall costs for these drugs, are particularly sensitive to the increasing prices of these life-saving medications. This is especially true in the biologics market, where the costs of the biologic vastly exceed those of traditional prescription drugs. In this context, the Court must be especially mindful of Congress's primary goals in passing the BPCIA – to facilitate prompt market entry of biosimilars to lower biologics costs while offering an incentive to produce new and innovative biologics in the future.

Respondent posits that biosimilar applicants can only provide the required notice of commercial marketing *after* the FDA approves the biosimilar for public distribution; the Court's adoption of this theory would unbalance Congress's careful compromise between competing demands and impose unnecessary barriers to lower-cost biosimilars.

ARGUMENT

I. BIOLOGIC DRUGS ARE OF CRITICAL IMPORTANCE TO CONSUMERS BUT IMPOSE A HIGH COST TO CONSUMERS AND TAXPAYERS GENERALLY AND TO OLDER ADULTS IN PARTICULAR.

In the past seven years alone, nationwide spending on prescription drugs is estimated to have increased by over $100 billion. U.S. Dep't of Health and Human Servs., Ofc. of Asst. Sec'y for Planning and Evaluation, *Observations on Trends in Prescription Drug Spending*, 8, tbl. 1 (Mar. 8, 2016), https://aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf. A large portion of those costs are borne by older adults, who, as a group, have the highest rate of prescription drug use due to the higher incidence of chronic diseases amongst older adults. Ctrs. for Disease Control & Prevention, *Health, United States, 2015: With Special Feature on Racial and Ethnic Health Disparities*, 168 and 272, tbls. 39 and 79 (2016), http://www.cdc.gov/nchs/data/hus/hus15.pdf.

The pace of ever-increasing drug prices, as well as the increased share of costs borne by consumers, has

a direct impact on consumers' behavior. In addition to their obvious financial implications, high drug prices affect consumers' compliance with their medication regimen. According to the National Center for Health Statistics, consumers age 18-64 were almost twice as likely as adults age 65+ to skip doses, take less medication, or delay filling prescriptions to save money. U.S. Dept. of Health and Human Servs., Nat. Ctr. for Health Stats., *Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States, 2013*, 2 (Jan. 2015), https://www.cdc.gov/nchs/data/databriefs/db184.pdf. Individuals age 18-64 who are either uninsured or have coverage through Medicaid are more likely to unilaterally curtail their prescription drug usage, even against the explicit instructions of their physician. *Id.* at 3. The poorest Americans—regardless of their age—are also more likely to avoid taking their prescription drugs as prescribed to limit costs. *Id.* at 4-5.

Biologics are quickly emerging as a vital tool in the fight against many chronic and life-threatening conditions that acutely or disproportionately affect older adults, including arthritis and cancer. Steven Kozlowski, et al., *Developing the Nation's Biosimilar Program*, 365 New Eng. J. Med. 385, 386 (Aug. 4, 2011), http://www.nejm.org/doi/pdf/10.1056/NEJMp1107285. *See also* Nathan A. Berger, et al., *Cancer in the Elderly*, 117 Transactions of the Am. Clinical & Climatological Ass'n 147, 148 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1500929/pdf/tacca117000147.pdf (stating that "persons over 65 account[] for 60% of newly diagnosed [malignant cancers] and 70% of all cancer deaths") *and* Ctrs. for Disease Control &

Prevention, *Arthritis-Related Statistics* (*last accessed* Feb. 14, 2017), https://www.cdc.gov/arthritis/data_statistics/arthritis-related-stats.htm (finding that "the risk of arthritis increases with age").

Unfortunately, the potential of biologics to treat life-threatening conditions comes at a steep cost to consumers, taxpayers, and insurers, as the prices for these drugs far exceed those of traditional prescription drugs, with some companies charging $200,000 a year or more. Francis Megerlin, et al., *Biosimilars and the European Experience: Implications for the United States*, 32 Health Aff. 1803 (Oct. 2013). Even among insured individuals with prescription drug coverage, a consumer's out-of-pocket cost for biologics tends to be higher than many traditional prescription drugs, as biologics are frequently placed on higher cost-sharing tiers that impose higher co-pays or co-insurance requirements of up to 50% of the drug's price. *Letter from AARP to Federal Trade Commission Re: Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901*, 2 (Dec. 22, 2008), https://www.ftc.gov/sites/default/files/documents/public_comments/emerging-health-care-competition-and-consumer-issues-537778-00034/ 537778-00034.pdf.

Increasing demand for biologic drugs has allowed them to buck general downturns in prescription drug spending trends. In 2012, while overall U.S. spending on prescription drugs decreased from the preceding year, spending on so-called "specialty drugs," mostly biologics, continued to climb by nearly 20%. Erwin A. Blackstone and Joseph P. Fuhr, *The Economics of Biosimilars*, 6 Am. Health &

Drug Benefits 469, 473 (Sept./Oct. 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/pdf/ahdb-06-469.pdf. Biologics manufacturers frequently argue that their prices merely reflect higher costs of obtaining approval for and manufacturing a biologic. *See, e.g.*, Mustaqeem Siddiqui, M.D., et al., *The High Cost of Cancer Drugs and What We Can Do About It*, 87 Mayo Clin. Proc. 935, 936 (Oct. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538397/pdf/main.pdf. (estimating "$1.2 billion to $1.3 billion in cash outlays" per approved biologic). Nonetheless, the high prices charged for biologics can allow their manufacturers to recoup development costs within a single year. AARP Pub. Pol'y Inst., *Biologics in Perspective: The New Biosimilar Approval Pathway* (Oct. 2011), http://assets.aarp.org/rgcenter/ppi/health-care/fs238.pdf.

With over 250 biologic drugs currently on the market and approximately 300 in development, the role of biologics in the health care system continues to expand with each passing year. AARP Pub. Pol'y Inst., *Biologics in Perspective: The Case for Generic Biologic Drugs* (May 2009), http://assets.aarp.org/rgcenter/health/fs155_biologics.pdf. Not only does the number of biologics continue to grow, but manufacturers of existing biologic drugs also seek approval to use them in treating additional diseases. For example, manufacturers of the biologic Avastin, originally approved in 2004 in the treatment of colon, lung, and breast cancers, sought FDA approval for the use of Avastin to treat 23 additional diseases. *Id.* By 2020, biologics are expected to account for 28% of the global prescription drug market. IMS Inst. for Healthcare Informatics, *Delivering on the Potential of Biosimilar*

Medicines: The Role of Functioning Competitive Markets, 1 (Mar. 2016), http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Documents/IMS_Institute_Biosimilar_Brief_March_2016.pdf.

Given the prominent and growing role of biologics in the health care system, it is vital to consumers and taxpayers that the marketplace allows for the prompt entry of competing products that would lower the prices of—and thus, increase access to—these drugs. Competition between biologics and biosimilars has a demonstrable effect on prices for these drugs. For example, in the course of this litigation, Zarxio initially sought to enter the market at a 15% discount off the price of Neupogen. Reuters, *Novartis Launches First U.S. "Biosimilar" Drug At 15 Percent Discount* (Sept. 3, 2015), http://www.reuters.com/article/us-novartis-drug-idUSKCN0R30C220150903.

At the time of the BPCIA's passage, the Congressional Budget Office estimated that the Act would save consumers, taxpayers, and insurers approximately $25 billion between 2009 and 2018. Cong. Budget Ofc., *Cost Estimate: Biologics Price Competition and Innovation Act of 2007* (June 25, 2008), https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/costestimate/s16950.pdf. More recent estimates show that biosimilars have the potential to save the U.S. health care system $44.2 billion by 2024. Rand Corp., *The Cost Savings Potential of Biosimilar Drugs in the United States* (2014), http://www.rand.org/pubs/perspectives/PE127.html. Other stakeholders predict even greater savings

from biosimilars. For example, a recent analysis by Express Scripts, one of the nation's largest pharmacy benefit managers, predicts that U.S. consumers, taxpayers, and insurers would save $250 billion by 2024 if the 11 biosimilars most likely to enter the market actually did so. Express Scripts, *The $250 Billion Potential of Biosimilars* (April 23, 2013), http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars.

Although biosimilars are a relatively new development in the U.S. health care system, the European experience with biosimilars may provide some insight as to the cost savings achieved by prompt consumer access to biosimilars. Since European authorities approved the first biosimilar in 2006, biosimilars have proven to increase both access and cost effectiveness. QuintilesIMS, *Biosimilars by Region—Europe* (*last accessed* Feb. 14, 2017), http://www.quintiles.com/microsites/biosimilars-know ledge-connect/biosimilars-by-region/europe. By 2013, biosimilars comprised approximately 25 percent of total sales of biologics with expired European Union patents. *Id.* Between 2006 and 2014, biosimilars increased patient access to biologics by 44 percent in France, Germany, Italy, Spain and the U.K. *Id.* Furthermore, the availability of biosimilars resulted in mean price discounts of 15 to 40 percent off the prices of the original biologics. *Id.*

This case comes before the Court during an unprecedented opportunity for more widespread entry of biosimilars to compete with and lower the cost of biologics. While the FDA has approved only four

biosimilars through the BPCIA process to date, by 2019, biologics with a combined market value of $50 billion are expected to lose protection of their underlying patents. Ctr. for Drug Eval. and Research, *List of Licensed Biological Products* (*last updated* Dec. 15, 2016), http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM439049.pdf; AARP Pub. Pol'y Inst., *A Sense of Déjà Vu: The Debate Surrounding State Biosimilar Substitution Laws* (Sept. 2014), http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/2014/the-debate-surrounding-state-biosimilar-substitution-laws-AARP-ppi-health.pdf. If the Court adopts the interpretation of the BPCIA proposed by Respondent Amgen, the chance for consumers and taxpayers to benefit from the cost savings brought on by broader market entry of biosimilars will be unnecessarily delayed.

II. THE FEDERAL CIRCUIT'S RULING UPSETS CONGRESS'S INTENDED BALANCE BETWEEN ENCOURAGING INNOVATION AND CONTROLLING COSTS.

As this Court has made abundantly clear, the "words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *King v. Burwell*, 135 S. Ct. 2480, 2492 (2015). The Federal Circuit's opinion holds that a biosimilar applicant "may only give effective notice of commercial marketing [under 42 U.S.C. § 262(l)(8)] *after* the FDA has licensed its product." *Amgen, Inc.*

v. Sandoz, Inc., 794 F.3d 1347, 1357 (Fed. Cir. 2015) (emphasis added). Judge Chen's dissenting opinion correctly frames this holding as a "180-day exclusivity windfall" for biologics manufacturers that appears nowhere in the actual statute. *Id.* at 1371 (Chen, J., dissenting in part). The Federal Circuit's opinion on this point has no basis in the text or structure of the BPCIA and is contrary to Congress's explicit objectives in its passage.

As with the Hatch-Waxman Amendments that concern the approval of generic drugs and resulting patent litigation process, the process outlined in the BPCIA resolves questions as to the timing and degree of overlap between the resolution of patent disputes and the FDA's approval process. *See* 21 U.S.C. § 355(j) (describing the process for approval of generic drugs). When Congress initially considered establishing a "pathway" for approval of biosimilars, these issues led to widely divergent opinions. Some stakeholders testified that the process agreed upon by Congress should include "a mechanism for allowing generic companies to resolve certain patent disputes without delaying FDA approval." *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the H. Subcomm. on Health of the Comm. on Energy and Commerce*, 110th Cong., 117 (May 2, 2007) (hereinafter *Assessing the Impact*) (testimony of Bruce Downey, Chairman, Generic Pharmaceutical Association). Others concluded that the "biosimilar applications should not be approved until all patent disputes had been resolved." Krista Carver, et al., *An Unofficial Legislative History of the Biologics*

Price Competition and Innovation Act of 2009, 65 Food and Drug L. J. 671, 736 (2010) (hereinafter *Unofficial History*) (summarizing the testimony of David Schenkein, M.D., Vice President of Clinical Hematology and Oncology at Genentech, Inc.). Others proposed a total "decoupling" of the patent litigation process from the biosimilar licensure process. *Examining Food and Drug Administration Follow-On Biologics: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 110th Cong., 36 (March 8, 2007) (testimony of Ajaz S. Hussain, Ph.D., Vice President of Biopharmaceutical Development, Novartis). As enacted, the BPCIA adopts Dr. Hussain's approach.

The structure of the BPCIA belies Respondent's argument that the 180-day notice of a manufacturer's intent to market a biosimilar can only be provided *after* the FDA approves the application to license the biosimilar. The process and standards by which the FDA can license biosimilars are described at length at 42 U.S.C. § 262(k). Innovator biologics manufacturers enjoy both a twelve-year period of market exclusivity, as well as a four-year ban on the submission of applications to license a biosimilar. 42 U.S.C. § 262(k)(7). This section also describes the mandatory contents of an application to produce a biosimilar, as well as the standards by which a biosimilar can be deemed "interchangeable" with the biologic. 42 U.S.C. § 262(k)(2)-(4). However, at no point does this section purport to govern the resolution of patent infringement claims that may be filed during this process.

The resolution of patent litigation that may be triggered by an application to produce a biosimilar under 42 U.S.C. § 262(k) is described separately in the statute. 42 U.S.C. § 262(l). This process has its own specific timeframes and expectations of litigants at various points in the litigation process. 42 U.S.C. § 262(l)(1)-(7). This section does not describe or dictate the standards for approval of a biosimilar applicant, nor does it purport to alter the periods of market exclusivity granted to biologics manufacturers. Only at the end of this section is there language that tangentially references the outcome of the FDA's approval process. 42 U.S.C. § 262(l)(8)(A). However, in context, this language merely reflects a practical consideration that biosimilars must be, in fact, approved by the FDA before commercial marketing of biosimilars can actually begin.

The most sensible way to interpret the notice of commercial marketing provision in 42 U.S.C. § 262(l)(8) is that the process by which the FDA licenses a biosimilar under subsection (k) runs *parallel* to the patent litigation process under subsection (l). Ultimately, the FDA must approve the biosimilar before it can be marketed to the public, irrespective of where the parties are in the patent litigation process. 42 U.S.C. § 262(k)(3). Congress did not intend to penalize biosimilars manufacturers for their readiness to bring their products to market immediately upon their approval by the FDA.

Congress knew of the complexities of patent litigation in the pharmaceutical context when it

enacted the BPCIA. To speed up the market entry of biosimilars, Congress adopted the proposal by some stakeholders that the process designed by Congress should not "force[]" biosimilars manufacturers "to litigate every patent relating to the brand product" in order to clear the way for a biosimilar's launch. *Assessing the Impact* at 119 (testimony of Bruce Downey). In other words, Congress adopted the view proposed by some stakeholders that the BPCIA should contain "a mechanism for litigating only those patent disputes that the generic company believes would delay its launch," because litigation of other patents would cause "unnecessary delay." *Unofficial History* at 736. According to the Biotechnology Innovation Organization, the purpose of granting market exclusivity to a biologics manufacturer would be to provide an "insurance policy" for "instances where the [biosimilar] manufacturer is able to work around the patents held by the innovator but still gain approval of its [biosimilar]." *Id.* at 727. It has nothing to do with the status of the FDA's approval of the biosimilar.

Congress intended the BCPIA to represent a "balanced approach" between satisfying the need for affordable, safe, and effective biosimilars with the need to incentivize innovation by biologics manufacturers. Sen. Comm. On Health, Education, Labor, and Pensions, *Press Release: Lawmakers Praise Committee Passage of Biologics Legislation* (June 27, 2007), http://www.help.senate.gov/ranking/newsroom/press/lawmakers-praise-committee-passage-of-biologics-legislation; *see also Assessing the Impact* at 19 (statement of Rep. Towns). To that end,

Congress envisioned a process to facilitate FDA approval of biosimilars, while abbreviating patent litigation in a manner comparable to the system that exists for generic drugs under the Hatch-Waxman Act, with the ultimate goal to produce "measurable savings" to consumers, taxpayers, and insurers. *Assessing the Impact* at 2 (statement of Rep. Pallone).

Congress intended the BPCIA's twelve years of commercial marketing exclusivity for biologics manufacturers to represent a rough approximation of the average years of market exclusivity already enjoyed by biologics manufacturers. *Biologics and Biosimilars: Hearing Before the House Subcomm. on Courts and Competition Pol'y* 111th Cong., 8 (July 14, 2009) (testimony of Rep. Eshoo). At that time, Congress considered widely varying proposals for market exclusivity, with some stakeholders recommending a period of as long as 14 years, and others recommending a period as short as five to seven years. *Unofficial History* at 817. The twelve years ultimately settled on by Congress represents the culmination of years of negotiations between various stakeholders.

For its part, the FDA views its own responsibilities as independent of the patent litigation and market exclusivity issues described above. In the words of the FDA's Center for Drug Evaluation and Research, the BPCIA is merely a mechanism to "improve access" to biosimilars by creating an "abbreviated pathway" to their licensure that "will eliminate unnecessary...testing of biosimilars in animals and humans." Kozlowski,

supra at 385. In the FDA's view, the process established by the BPCIA "permits a biosimilar...to rely on certain existing scientific knowledge about the safety and effectiveness of the [original biologic]...saving the sponsor time and resources and thereby encouraging price competition and lower consumer healthcare costs." U.S. Food and Drug Administration, *Biosimilars Implementation: Hearing Before Subcomm. on Health of the Comm. on Energy and Commerce, U.S. House of Representatives*, 2 (Feb. 4, 2016) (testimony of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research), http://www.fda.gov/downloads/NewsEvents/Testimony/UCM485049.pdf. As it continues to apply the approval process described by the BPCIA, the FDA's concern strictly rests with "earn[ing] and sustain[ing] both physicians' and patients' confidence in biosimilar and interchangeable products [by applying] a scientifically rigorous review process and approval standard." *Id.* at 1.

CONCLUSION

As the Northern District of California observed in this case, if Congress truly intended to extend an additional 180 days of market exclusivity to biologics, "it could not have chosen a more convoluted method of doing so." *Amgen, Inc. v. Sandoz, Inc.*, 2015 U.S. Dist. LEXIS 34537, *25 (Mar. 19, 2015). The Federal Circuit's opinion creates unnecessary delays to public access of biosimilars, and in so doing harms consumers and taxpayers. Because Congress had no

intention to do so, the Federal Circuit's decision to the contrary should be reversed.

Respectfully submitted,

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RECORD AND BRIEFS

FILED
MAR 17 2023
OFFICE OF THE CLERK
SUPREME COURT, U.S.

Nos. 15-1039 and 15-1195

In the Supreme Court of the United States

SANDOZ INC.,
Petitioner,
v.
AMGEN INC., ET AL.,
Respondents.

AMGEN INC., ET AL.,
Petitioners,
v.
SANDOZ INC.,
Respondent.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR ABBVIE INC. AS AMICUS CURIAE IN SUPPORT OF AMGEN INC., ET AL.

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Journal of Commerce

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INTERESTS OF AMICUS CURIAE[1]

AbbVie Inc. is an innovative biopharmaceutical company that discovers, develops, and markets drugs for the treatment of many diseases, including HIV, hepatitis C, cancer, multiple sclerosis, Parkinson's disease, and immunological diseases. One of AbbVie's drugs, HUMIRA® (adalimumab), was the first fully-human antibody to be approved by the Food and Drug Administration (FDA). HUMIRA® has been used to treat over one-million patients suffering from diseases as diverse as rheumatoid arthritis, psoriasis, and Crohn's disease.

HUMIRA® is one of a growing category of drugs known as biologics. Biologics are complex proteins manufactured in living cells rather than by chemical synthesis. Biologics can treat diseases very effectively, but are difficult to develop and manufacture because of their complexity. AbbVie's clinical research on HUMIRA® has included over 100 clinical trials and resulted in FDA approval for the treatment of ten different diseases. While Sandoz, Inc. and several of its amici call out HUMIRA® as an example of the high cost of biologics and emphasize how expensive it is to develop a *biosimilar* product, those expenditures pale in comparison to the expense and risk AbbVie took on in developing its original, pioneering biologic.

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[1] The parties have consented to the filing of this amicus brief. No counsel for any party authored this brief in whole or in part; and no such counsel or any party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than amicus and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

HUMIRA® is the subject of biosimilar applications under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, §§ 7001-03, 124 Stat. 119, 804-21 (2010). On September 23, 2016, Amjevita, the first biosimilar for HUMIRA®, was approved by the FDA. Amjevita has not been commercially released; it is currently the subject of patent litigation, and no notice of commercial marketing has yet been provided. Amjevita is one of only four biosimilars that have been approved by the FDA to date. Many other companies, including Sandoz, have announced that they will also be seeking FDA approval for biosimilars to HUMIRA®. Moreover, AbbVie has developed and will continue to develop new biologics that likely will be the subject of biosimilar applications under the BPCIA. AbbVie thus has a significant interest in ensuring a fair system of resolving patent disputes surrounding the approval of biosimilar products, as well as real-world experience operating under the BPCIA notice-and-exchange procedures at issue in this case.

INTRODUCTION AND SUMMARY OF ARGUMENT

There are two overarching issues in this case: (1) what the BPCIA requires in terms of the notice-and-exchange process, and (2) what a reference product sponsor can do if a biosimilar applicant fails to comply with those requirements. The answer to the first question is straightforward: at the front end, applicants are required to provide their abbreviated Biologics License Applications (aBLA) and manufacturing information to the reference product sponsor; at the back end, they are required to provide 180 days' notice of commercial marketing after FDA

licensure. The second question is not properly presented and need not be decided by the Court.

On the first question, Sandoz and its amici argue that Congress created an entirely discretionary notice-and-exchange process whereby biosimilars can opt-out at any time and provide "notice" (if at all) months or even years before any possible launch. Sandoz tries to portray that scheme (which bears no resemblance to the one Congress actually enacted) as entirely reasonable and consistent with what "rational" actors would do. But Sandoz's account is inconsistent with the FDA approval process, contradicted by real-world events, and premised on potential exceptions to a generally applicable rule. In the end, a discretionary "notice" of commercial marketing that has no temporal nexus to actual commercial marketing is the functional equivalent of no notice at all.

On the second question, Sandoz and its amici ask this Court to hold that, where an applicant violates the BPCIA's notice-and-exchange provisions, there is no *federal* private right of action to enforce the statute. But that question is not presented here: Amgen, Inc. brought only *state*-law claims to enforce the BPCIA. Thus, the only salient question that could be before the Court is whether Amgen's state-law claims are preempted by the BPCIA. Sandoz, however, has expressly disavowed any preemption defense and, accordingly, has waived that argument, which leaves this Court with an exceedingly unsuitable vehicle to resolve the enforcement question. To the extent the Court wishes to decide the issue at all, preemption is the correct framework and Amgen's state-law claims are not preempted. But the more prudent course would be to affirm Amgen's interpretation of the

statute and leave the means of enforcement for another day.

ARGUMENT

I. SANDOZ'S ACCOUNT OF HOW THE BPCIA SHOULD WORK IS INCOMPLETE AND INCONSISTENT WITH THE ACTUAL STATUTE

This Court should affirm the Federal Circuit's unanimous holding that the 180-day notice of commercial marketing cannot be provided before FDA licensure. Amgen's brief persuasively explains why the plain text, statutory structure, and legislative history compel that reading. *See* Amgen Br. 27-42.[2] That should be the end of the analysis.

Sandoz and its amici, however, expend considerable energy painting a misleading picture of the patent litigation and FDA approval process undergirding the BPCIA. From the information available to reference product sponsors during the FDA approval process, to when biosimilars would choose to provide commercial notice if given such discretion, to what patents remain to be litigated during the 180-day notice period, the topside briefs tell an incomplete story at best. To place the Court's statutory interpretation task in its proper context, this brief addresses just a few of the many holes in that tale. In the end, congressional intent remains the touchstone and provides the answer:

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[2] For example, 42 U.S.C. § 262(*l*)(8)(A) critically refers to the biological product "licensed" under subsection (k), not the biological product "that is the *subject of*" an application under subsection (k), as elsewhere in the statute when Congress so intended. *See* Amgen Br. 28-31.

Congress created a detailed, sequential, and mandatory notice-and-exchange process to streamline patent litigation before commercial launch.[3]

A. The BPCIA Is In Its Infancy

In evaluating Sandoz's speculation about what stakeholders will and will not do if given the choice, it is important to remember that the BPCIA is a new statutory scheme. It was enacted as part of the Patient Protection and Affordable Care Act in 2010. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). And the FDA did not issue its first guidance on the BPCIA biosimilar pathway until 2012. Leah Christl, U.S. Food and Drug Administration, *FDA's Overview of the Regulatory Guidance for the Development and Approval of Biosimilar Products in the US* 15, https://tinyurl.com/hmmpnv3 (last visited Mar. 15, 2017).

To the best of AbbVie's knowledge, the first biosimilar application was not submitted to the FDA until 2014.[4] From 2014 until the Federal Circuit's July 21, 2015 decision in this case, the FDA received only five known applications: from Sandoz (for Amgen's

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[3] While not the primary focus of this brief, AbbVie also agrees with Amgen that the Federal Circuit was wrong to hold that Section 262(*l*)(2)(A) is optional. The statutory command that a biosimilar applicant "shall" provide its application and manufacturing information to the reference product sponsor is mandatory, as even the United States concedes. *See* U.S. Amicus Br. 16.

[4] Because the aBLAs are not public (*see infra* at 8), only the FDA knows for certain what applications have been filed and when.

Neupogen®), Celltrion (for Janssen's Remicade®), Apotex (for Amgen's Neulasta® and Neupogen®), and Hospira (for Amgen's Epogen®). *See* Addendum A (chart detailing these subsection (k) applications with corresponding cites). Based on publicly available information, it appears that a total of between one and two dozen subsection (k) applications have been submitted to the FDA.[5]

To date, the FDA has approved only four biosimilars through the subsection (k) abbreviated pathway:

- Sandoz's Zarxio, a biosimilar of Amgen's Neupogen (approved March 6, 2015);[6]
- Celltrion and Pfizer's Inflectra, a biosimilar of Janssen's Remicade (approved April 5, 2016);[7]

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[5] Eastern Research Group, Inc., *Review of Biosimilar Biologic Product Applications: Study of Workload Volume and Full Costs*, Final Results Report 4 (Feb. 24, 2016), https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM488846.pdf (seven applications filed through 2015); Biosimilar Review & Report, *US 351(k) Biosimilar Filings: Biosimilar Drug Status In The US: FDA Filing Dates And Actions* (2017), https://biosimilarsrr.com/us-biosimilar-filings/ (counting fourteen public applications).

[6] News Release, U.S. Food & Drug Administration, *FDA approves first biosimilar product Zarxio* (Mar. 6, 2015), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm436648.htm.

[7] News Release, U.S. Food & Drug Administration, *FDA approves Inflectra, a biosimilar to Remicade* (Apr. 5, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm494227.htm.

- Sandoz's Erelzi, a biosimilar of Amgen's Enbrel (approved August 8, 2016);[8] and
- Amgen's Amjevita, a biosimilar of AbbVie's HUMIRA® (approved September 23, 2016).[9]

And for the last 20 months, biosimilar applicants and reference product sponsors have operated under the Federal Circuit's decision in this case. In fact, the *only* biosimilar approved by the FDA before the Federal Circuit's decision was the one at issue here.

Accordingly, virtually all of the actual examples Sandoz and its amici point to played out in a world where the Federal Circuit's interpretation of the BPCIA was the controlling law. Any predictions about "rational" party behavior based on this exceedingly small and skewed data set are thus of limited value, and give no insight as to what biosimilar applicants will do if the commercial-marketing notice requirement is marginalized or effectively nullified.

B. The BPCIA In Practice Bears Little Resemblance To Sandoz's Account

There are many flaws in Sandoz's story, but three are of particular note: (1) Sandoz's claim that the Court should not be concerned about the lack of transparency under its approach because all relevant information

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[8] News Release, U.S. Food & Drug Administration, *FDA approves Erelzi, a biosimilar to Enbrel* (Aug. 30, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm518639.htm.

[9] News Release, U.S. Food & Drug Administration, *FDA approves Amjevita, a biosimilar to Humira* (Sept. 23, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm522243.htm.

about the biosimilar application is publicly available; (2) Sandoz's claim that post-licensure notice of commercial marketing is meaningless whereas pre-licensure notice is meaningful; and (3) Sandoz's claim that the possibility that there will be no patents left to litigate during the 180 days makes post-licensure notice problematic. Aside from their speculative nature, Sandoz's claims are refuted by real-world examples and inconsistent with the framework Congress envisioned and enacted.

1. Sandoz first claims that a "sponsor would know about the filing of [a biosimilar] application even when the applicant did not provide a copy." Sandoz Br. 48. But it is undisputed that the aBLA is neither publicly filed nor otherwise available to the reference product sponsor. The same is true of the manufacturing information that the BPCIA directs "shall" be provided with the aBLA. 42 U.S.C. § 262(*l*)(2)(A).

Sandoz's contention, instead, is that a sponsor would (or could) cobble together sufficient information from SEC filings, press releases, clinical trial data, and FDA public meetings to conclude that a filing had (likely) occurred. Sandoz Br. 48-51. Even taking that infirm assumption as true, none of those sources would include the content of the aBLA itself, let alone the manufacturing information. Thus, the sponsor would know nothing about the manufacturing of the product, its formulation, or its indicated uses—all of which are paramount in determining whether the sponsor's patent rights have been trespassed upon.

Moreover, the detailed notice-and-exchange process Congress envisioned looks nothing like the haphazard and piecemeal process Sandoz now advocates:

- The BPCIA: the biosimilar applicant "shall" provide the aBLA and manufacturing information to the sponsor within 20 days. 42 U.S.C. § 262(*l*)(2)(A).
- Sandoz: the sponsor should instead scour a variety of different sources to try to divine whether an aBLA had been filed and patch together a complaint based on the minimal information contained in those sources.

Congress plainly intended there to be a more transparent, informed, and streamlined approach to early patent litigation. *See, e.g., Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 9 (2009) (statement of Rep. Anna G. Eshoo) (the proposed notice-and-exchange provisions "will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product"); *id.* at 8-9 (explaining the bill's "simple, streamlined patent resolution process"); Letter from C. Landis Plummer, Acting Sec'y, FTC, to Rep. Frank Pallone, Jr. 6-9 (May 2, 2008) (advising that biologics legislation includes a "pre-marketing patent litigation process" that "involve[s] private exchange of patent information").

2. Sandoz next claims that the "Federal Circuit's rule permitting 'notice' only after FDA approval also deprives Section 262(*l*)(8)(A) of any *notice* function." Sandoz Br. 41. The reason, according to Sandoz, is that "the FDA itself provides public notice that a biosimilar may be commercially marketed." *Id.* In other words, Sandoz views FDA approval as the equivalent of notice of commercial marketing. There are several problems

with this approach and, in the end, it is Sandoz's interpretation that deprives Section 262(*l*)(8)(A) of any true "notice" function.

First, Sandoz's argument conflates the product submitted as part of the aBLA with the final product approved by the FDA, and elides important distinctions between the two. But things can and do change between the filing of the aBLA and approval of the final product. *See* Amgen Br. 24 (noting that Sandoz's application was amended 30 times). For example, the indicated uses could be modified, either in terms of the diseases to be treated or the regimen used to treat those diseases, as could the formulation, delivery system, or manufacturing process. If biosimilars could launch immediately upon FDA approval, there would be no time to litigate patent infringement issues implicated by the approved biosimilar but not apparent from the face of the aBLA submitted many months, if not years, prior.

As Amgen explains, the BPCIA contemplates and provides for two phases of patent litigation. In the first phase, the parties "identify patent claims that can meaningfully be adjudicated or otherwise resolved before the FDA determines what, precisely, will be licensed." Amgen Br. 15. In the second phase, the parties can litigate the remaining patent claims including both (1) those identified in the notice-and-exchange process but not chosen for phase-one litigation, and (2) new patents issued to or exclusively licensed to the reference product sponsor after providing the initial list. *Id.* Sponsors need the 180-day notice window to compare the approved product to the aBLA, identify any remaining patent disputes, and (if needed) to file a preliminary injunction.

Second, FDA approval does not necessarily mean that commercial launch will immediately follow. Rather, a biosimilar might choose to wait for a period of time after FDA approval before giving commercial-marketing notice in order to delay litigating the remaining patents. Unlike Sandoz's examples, this is not fanciful speculation; it has *actually* occurred. As noted above, Amjevita, Amgen's biosimilar for HUMIRA®, was approved by the FDA on September 23, 2016. *See supra* at 7 n.9. Yet Amgen (the biosimilar applicant in that case) still has not given notice of commercial marketing nor has it launched. As such, AbbVie cannot yet assert its phase-two patents. The Amjevita situation thus proves unequivocally that a post-licensure notice provision is *not* duplicative of the announcement that the FDA has issued a license.

Third, it is Sandoz's reading that deprives Section 262(*l*)(8)(A) of a true "notice" function. Early "notice" of commercial marketing—months or even years before FDA approval—is no notice at all. At that point, nobody knows what (if anything) will ultimately be approved and marketed or when (or if) such marketing will occur. Indeed, as Amgen explains, "[i]t is not clear how an applicant can provide 'notice' of marketing when a condition precedent to marketing—namely, licensure—is wholly dependent on FDA action." Amgen Br. 33.

If the sponsor filed a motion for a preliminary injunction under Section 262(*l*)(8)(B) at that time, before launch is imminent (or even likely), the case for infringement and irreparable harm would look dramatically different. The United States goes so far as to claim that the preliminary injunctive relief central to the Section 262(*l*)(8) notice provision is not available

at all until launch is "imminent." U.S. Amicus Br. 18; *id.* at 13 ("Declaratory relief is the only relief available in such an action brought any significant amount of time before a biosimilar's commercial marketing."); *id.* at 23-24 & n.7 ("[A] sponsor cannot bring an artificial-infringement action for [injunctive] relief any significant amount of time before a biosimilar's commercial marketing. . . . [S]uch traditional equitable relief would be available only when [manufacture, use, or sale] are sufficiently real and imminent."). But that only proves that the premature "notice" of commercial marketing advocated by Sandoz cannot possibly be correct. After all, under Sandoz's approach, sponsors would never know that launch is imminent enough to warrant injunctive relief until the launch has already occurred. And that flat-out defeats the purpose of providing for orderly patent litigation before commercial launch. The BPCIA sets forth a process of post-licensure notice followed by a pre-launch preliminary injunction on a concrete dispute (where appropriate), not premature "notice" with no ability to enjoin launch followed by a rush to the courthouse to get a last-minute temporary restraining order upon announcement of FDA approval. *See* Amgen Br. 38-42.

Sandoz never explains what "notice" function pre-licensure notice as early as the day the aBLA is filed could possibly serve. If the goal is to litigate all patent disputes (then-existing and apparent from the aBLA) before FDA approval, the biosimilar applicant already has that power. It can simply choose to litigate *all* such patent claims in phase one, under Sections 262(*l*)(3)(B) and 262(*l*)(5)(A). The notice instead serves a different purpose: to permit time to litigate remaining patent disputes based on the final, approved

product when launch is fairly imminent. "Notice" that a biosimilar applicant may someday market a biosimilar if licensed at some unknown date in the future is meaningless. In reality, it is no notice at all.

Sandoz's response: no rational biosimilar applicant would provide such early notice. Specifically, Sandoz speculates that an applicant would not "behave so irrationally—providing its application to the sponsor (thus triggering the process meant to narrow and allow it to control the scope of immediate litigation) while simultaneously eliminating the value of that narrowing process by providing its notice of commercial marketing (thus inviting immediate litigation on any and all patents)." Sandoz Br. 38-39.

But Sandoz's speculation is demonstrably false. This "irrational[]" hypothetical has in fact occurred in the *majority* of cases to date. AbbVie is aware of only five total instances in which a biosimilar applicant has provided *any* notice of commercial marketing. In two (Hospira's biosimilar of Epogen and Apotex's biosimilar of Neupogen), the applicant provided the aBLA pursuant to Section 262(*l*)(2)(A) and then provided Section 262(*l*)(8)(A) notice of commercial marketing just five or six weeks later. *See* Addendum A. And in two others (Celltrion's biosimilar of Remicade and Apotex's biosimilar of Neulasta), the applicants gave their Section 262(*l*)(8)(A) notices less than four months after providing the aBLAs. *Id.* That is, in all four of these examples, the applicant gave notice of commercial marketing very soon after providing the aBLA, long before the notice-and-exchange processes were finished, and many months (or even years) before any prospect of actual launch. Indeed, nearly two years have since passed and three

of these biosimilars still have not been approved by the FDA. *Id.*

In short, true "notice" of commercial marketing can occur only when commercial marketing is reasonably imminent and the product to be marketed is actually known—*i.e.*, after FDA licensure.

3. Sandoz and its amici also repeatedly rely on the same two refrains: (i) post-licensure notice is an unwarranted extension of the 12-year period of exclusivity, and (ii) post-licensure notice will delay launch by 180 days even when there are no remaining patents to be litigated. *See, e.g.*, Sandoz Br. 6-7, 30, 33, 39-40, 56-60; U.S. Amicus Br. 29, 32; Apotex Amicus Br. 11, 14, 19.

Amgen explains the many reasons why these concerns are unfounded. *See* Amgen Br. 52-58. For example, Sandoz itself offered a proposal during the legislative process that would have similarly delayed market entry post-licensure to allow for orderly patent litigation. *Id.* at 53-54. Specifically, Sandoz (along with its corporate parent Novartis) proposed an exclusivity period of at least 12 years, followed by a post-licensure notice period during which time the biosimilar could not launch. *Id.* What Sandoz now claims is illogical is actually a fairly close replica of the regime it proposed.

And while Sandoz suggests that the 180-day notice period will be unnecessary when there are no patents left to litigate, Amgen explains that "it will be rare that a sponsor has no patents to assert" during that 180-day window. *Id.* at 56. As AbbVie can attest, sponsors often continue to innovate, develop their products, improve manufacturing processes, and invent new methods to treat patients long after discovery of the original therapeutic molecule. Indeed, when initially

approved in 2002, HUMIRA® was only indicated for the treatment of one disease, rheumatoid arthritis. Since then, due to AbbVie's continuing innovation, the FDA has approved HUMIRA® for the treatment of *nine* additional diseases. And the Patent and Trademark Office has issued 12 new patents relevant to Amgen's biosimilar of HUMIRA® since AbbVie provided its Section 262(*l*)(3)(A) list to Amgen.

AbbVie's case against Amgen provides a useful example of the work to be done during the 180-day notice period. AbbVie identified more than 60 patents during the BPCIA patent exchange process. Compl. ¶ 39, *AbbVie v. Amgen*, No. 16-cv-00666 (D. Del. Aug. 4, 2016). After going through notice-and-exchange, Amgen limited the initial litigation to just ten patents—as was its right under the BPCIA. *See id.* ¶¶ 8, 20. Accordingly, AbbVie must now wait until Amgen provides notice of commercial marketing to bring suit on the 50+ remaining patents. Once Amgen provides that notice, AbbVie will need the 180 days to seek, if necessary, a preliminary injunction.

Even if it turns out in other cases that there ultimately are no patents left to litigate in the second phase, there is still nothing illogical about a rule that imposes a 180-day post-licensure notice period. As discussed above, sponsors still need time to assess whether the final product violates additional patents or if the infringement analysis has changed based on the final, approved product. But more fundamentally, Congress created a generally applicable rule. That a general rule may not serve the congressional purpose in *every* case does not give courts license to rewrite it. *See, e.g., Califano v. Jobst*, 434 U.S. 47, 53 (1977) ("There is no question about the power of Congress to

legislate on the basis of such factual assumptions. General rules are essential . . . [for] efficiency, even though such rules inevitably produce seemingly arbitrary consequences in some individual cases.").

* * *

In the end, Sandoz's interpretation cannot be squared with the real-world behavior of applicants or the deliberate, sequential process Congress enacted. Indeed, even Sandoz and its amici are at odds on their proposed rule. Sandoz and the United States argue that Section 262(*l*)(8)(A) notice is *only* required if the applicant engaged in the notice-and-exchange process. Sandoz Br. 61-62; U.S. Amicus Br. 32-33. Apotex argues that notice of commercial marketing is *only* required if the applicant did *not* engage in the notice-and-exchange process. Apotex Amicus Br. 23. Neither reading comports with the statute as written; the notice of commercial marketing is mandatory in all circumstances. Congress certainly believed that the parties would engage in the notice-and-exchange process, since that is mandatory too. But either way, Congress intended to give sponsors an opportunity to assess the biosimilar *as licensed*, examine their patents (litigated or otherwise), and seek a preliminary injunction before launch.

II. THIS CASE DOES NOT PRESENT ANY QUESTION ABOUT FEDERAL PRIVATE RIGHTS OF ACTION

If the Court agrees with Amgen that the notice-and-exchange provisions are mandatory and that the 180-day notice of commercial marketing can only be given after the product is licensed, it can and should stop there. For all of the focus on *federal* private

rights of action in the topside briefs, that question is not presented here: the only claims Amgen brought to enforce the BPCIA were under state law.

The question that could have been presented—*i.e.*, whether those state-law claims are preempted by the BPCIA—was neither pressed nor passed on below. Sandoz affirmatively disavowed any reliance on a preemption defense and, for that reason, the Federal Circuit declined to address that argument.

Under these circumstances, the better course is to definitively resolve the statutory interpretation question and leave the issue of enforcement for another day. That approach is especially appropriate here because the injunction Sandoz challenges expired in September 2015. *See* Amgen Br. 5. Alternatively, if the Court chooses to address enforcement, Sandoz bears the burden of proving that the California state-law claims are preempted and it cannot make that considerably more stringent showing.

A. The Enforcement Question Is Not Properly Presented

Sandoz and the United States spend a significant portion of their respective briefs arguing that there is no *federal* private right of action. *See, e.g.*, Sandoz Br. 28-29, 43-48, 53-56; U.S. Amicus Br. 20-22, 35. But they never confront the fact that Amgen brought only state-law claims to enforce the BPCIA.[10] Specifically, Amgen alleged that Sandoz had violated California's Unfair Competition Law (UCL), Cal. Bus. & Prof.

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[10] Amgen also sued for patent infringement, and later amended its complaint to include an additional claim of infringement. Those federal claims remain pending in the district court. *See* Amgen Br. 22.

Code § 17200 *et seq.*, which prohibits any "unlawful, unfair or fraudulent business act or practice," and that Sandoz's use of Amgen's property to obtain a government privilege was an illegal act of conversion under California law. *See* Compl. ¶¶ 78-106, *Amgen v. Sandoz*, No. 14-cv-04741 (N.D. Cal. Oct. 24, 2014), ECF No. 1 ("*Amgen* Compl."). This Court should not decide whether a federal private right of action exists in a case where a federal claim was never alleged. *Cf. Atl. Coast Line R.R. Co. v. Glenn*, 239 U.S. 388, 393 (1915) ("[W]e confine ourselves to the case before us" and do not decide "questions [that] are not presented by the record.").

Rather, when the operative claims arise under state law, the relevant question is whether the BPCIA somehow *preempts* state law. But that question is not presented here either. Preemption is an affirmative defense that can be waived. *See Teutscher v. Woodson*, 835 F.3d 936, 945 n.1 (9th Cir. 2016) (finding waiver of preemption defense for failure to raise in district court or on appeal); *Russian Media Grp., LLC v. Cable Am., Inc.*, 598 F.3d 302, 309 (7th Cir. 2010) ("[F]ederal preemption [is] an affirmative defense" that can be "permanently waived."); *see also Wood v. Milyard*, 566 U.S. 463, 470 (2012) ("An affirmative defense, once forfeited, is excluded from the case." (internal quotation marks, alterations, and citations omitted)).

Critically, Sandoz has never argued that Amgen's state-law claims are preempted—not in the district court, the Federal Circuit, or this Court. Pet. App. 26a n.5 ("In its cross-motion for judgment on the pleadings, Sandoz did not argue preemption as a defense to Amgen's state law claims, and thus the district court did not consider that issue."). Indeed, Sandoz

affirmatively disavowed any such argument. CAJA1854 ("We have not argued preemption of the state law claims"). Because Sandoz never argued that Amgen's state-law claims were preempted, the Federal Circuit expressly declined to pass on that question. Pet. App. 26a n.5 ("We therefore do not address preemption in this appeal."). This Court should not decide an issue that was neither "pressed [n]or passed upon" below. *Youakim v. Miller*, 425 U.S. 231, 234 (1976) (per curiam) ("It is only in exceptional cases coming here from the federal courts that questions not pressed or passed upon below are reviewed." (citation omitted)).

B. Sandoz Cannot Prove That The BPCIA Preempts Amgen's State-Law Claims

If, despite Sandoz's clear waiver, this Court nevertheless chooses to address the enforcement question, familiar preemption case law provides the appropriate framework. Take Amgen's claim under the UCL, for example. The UCL allows recovery for "unlawful" business practices that harm a competitor. Cal. Bus. & Prof. Code § 17200 *et seq.* Amgen's complaint alleges that Sandoz acted unlawfully by, among other things, failing to provide the notice of commercial marketing required by Section 262(*l*)(8)(A). *Amgen* Compl. ¶ 80. If that conduct was "unlawful" (and it was), the only question is whether the UCL claim is preempted by the BPCIA.[11] It is not.

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[11] There can be no real dispute that a violation of the BPCIA constitutes "unlawful" conduct under the UCL. *See Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 539 (Cal. 1999) ("[T]he unfair competition law's scope is broad. . . . Its coverage is sweeping, embracing anything that can properly be

1. *The existence of a federal private right of action does not control the preemption analysis*

The United States asserts that, to enforce a federal statutory provision, "Congress must itself create a cause of action" and that the absence of such a cause of action is "fatal." U.S. Amicus Br. 14, 22. But States can create claims that incorporate federal law even where Congress has not created a federal private right of action. This is a well-established proposition. In *Bates v. Dow Agrosciences LLC*, for example, the Court explained that even though a federal statute did "not provide a federal remedy to [those] injured as a result of a manufacturer's violation of [the statute's] labeling requirements, nothing in [the statute] precludes States from providing such a remedy." 544 U.S. 431, 448 (2005).

Indeed, the United States previously told this Court as much in the context of comparable UCL claims. *See* Brief of the United States as Amicus Curiae 12-15, *Rose v. Bank of Am., N.A.*, 134 S. Ct. 2870 (2014), 2014 WL 2202864 ("*Rose* Br."); Brief for the United States as Amicus Curiae 11-14, *Albertson's, Inc. v. Kanter*, 555 U.S. 1097 (2009), 2008 WL 5151069 ("*Albertson's* Br."). In *Rose*, the United States explained that a federal statute cannot "foreclose a state-law action ... without a finding that Congress intended to 'preempt' state law." *Rose* Br. 10. "'The party who brings a suit is master to decide what law he will rely upon,' and therefore may sue under state law whether or not the same allegations would support a

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called a business practice and that at the same time is forbidden by law." (citation and internal quotation marks omitted)).

federal-law cause of action." *Id.* at 14-15 (citation omitted). Whether "Congress has provided a private right of action or a private remedy *under federal law*" is a "fundamentally different question" than whether Congress has preempted state law. *Id.* at 16. Simply put, "Congress's decision not to authorize a private action under federal law" does not "preclude[] a State from creating . . . a parallel or identical private action under state law." *Id.* This is true even when the federal statute expressly *prohibits* private enforcement actions. *See Albertson's* Br. 8 ("Although 21 U.S.C. 337 precludes private actions to enforce the [Federal Food, Drug, and Cosmetic Act (FDCA)] itself, Section 337 does not prohibit private actions to enforce parallel state requirements.").

The California Supreme Court has held likewise, rejecting the argument that UCL claims are preempted even when a federal right of action was indisputably unavailable. *See, e.g., Rose v. Bank of Am., N.A.*, 304 P.3d 181, 186 (Cal. 2013) ("It is settled that a UCL action is not precluded 'merely because some other statute on the subject does not, itself, provide for the action or prohibit the challenged conduct.'" (citation omitted)), *cert. denied*, 134 S. Ct. 2870 (2014); *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1180 (Cal. 2008) ("[I]t is undisputed that section 337 [of the FDCA] bars private enforcement of the FDCA .... However, plaintiffs do not seek to enforce the FDCA. Their action is based on the violation of *state law* . . . .").

Thus, the purported absence of a federal private right of action to enforce the notice-and-exchange provisions of the BPCIA has no bearing on whether Amgen's UCL claim is preempted.

2. *Any BPCIA "remedy" is not exclusive*

Similarly, any alleged "remedy" provided by the BPCIA would not preclude UCL enforcement. Under California law, the UCL "is meant to provide remedies *cumulative* to those established by other laws, absent express provision to the contrary." *Rose*, 304 P.3d at 187 (citing Cal. Bus. & Prof. Code § 17205). Indeed, California courts "have long recognized that the existence of a separate statutory enforcement scheme does not preclude a parallel action under the UCL." *Id.* (citing *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 950 P.2d 1086, 1098-99 (Cal. 1998)). UCL remedies are unavailable *only* if the underlying "statute itself provides that the remedy is to be exclusive." *State v. Altus Fin., S.A.*, 116 P.3d 1175, 1187 (Cal. 2005).

The BPCIA does not expressly provide an *exclusive* remedy for violating the 180-day commercial notice provision. The only provision of the statute that Sandoz identifies as a "remedy" is Section 262(*l*)(9)(B), which lifts the stay on a sponsor's ability to bring a declaratory judgment action if the applicant fails to follow certain steps in the notice-and-exchange process, including by failing to provide commercial notice. That provision is hardly remedial. An applicant cannot "fail" to give notice of commercial marketing unless and until it launches its product without notice. But once the product has launched, the sponsor can bring a garden-variety patent infringement suit under 35 U.S.C. § 271 anyway. Thus, Section 262(*l*)(9)(B) imposes *no* consequence for failing to give notice.

To the extent Section 262(*l*)(9)(B) can fairly be described as a "remedy" at all, it is not exclusive. "To forestall an action under the unfair competition law,

another provision must actually 'bar' the action or clearly permit the conduct." *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 541 (Cal. 1999). Thus, courts have generally required that the underlying statute *expressly* designate a remedy as "exclusive" in order to bar UCL relief. *Blue Cross of Cal., Inc. v. Superior Court*, 102 Cal. Rptr. 3d 615, 627 (Ct. App. 2009) ("[I]n order for a statute to deprive the city attorney of authority to sue under the UCL . . . , it must do so *expressly*."); *Stevens v. Superior Court*, 89 Cal. Rptr. 2d 370, 377 (Ct. App. 1999) (holding that relief under the UCL was not barred because the underlying statute "*does not expressly provide for exclusivity of its remedies*"); *see also People v. McKale*, 602 P.2d 731, 735 (Cal. 1979).

There is nothing in the BPCIA that so much as suggests that Congress intended Section 262(*l*)(9)(B) to be exclusive. The paragraph is entitled "Limitation on declaratory judgment action." 42 U.S.C. § 262(*l*)(9). The relevant subparagraph simply provides that a sponsor "may" bring a declaratory judgment action. *Id.* § 262(*l*)(9)(B). And, unlike earlier bills addressing biosimilars, there is no other provision limiting a court's ability to compel compliance with the 180-day notice requirement. *See* Amgen Br. 45. Because the BPCIA does not contain any remedy for failing to comply with the 180-day notice requirement, let alone an "exclusive" one, the UCL is available to provide a remedy for such "unlawful" conduct.

3. *The BPCIA does not preempt state law claims*

"[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citation omitted).

Courts find preemption in three circumstances: when there is an "express provision for preemption," "[w]hen Congress intends federal law to 'occupy the field,'" and when state law "conflict[s] with a federal statute." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (citation omitted). The BPCIA contains no express preemption provision. Nor does federal patent law preempt the entire field of unfair competition. *See Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1333 (Fed. Cir. 1998) ("[T]here is no field preemption of state unfair competition claims that rely on a substantial question of federal patent law.").

The UCL also does not conflict with or pose "an 'obstacle to the accomplishment and execution'" of federal objectives. *Wyeth*, 555 U.S. at 577 (citation omitted); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996). The Federal Circuit has explained that "[t]he patent laws will not preempt [state-law] claims if they include additional elements not found in the federal patent law cause of action and if they are not an impermissible attempt to offer patent-like protection to subject matter addressed by federal law." *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999). Amgen's state-law UCL claim includes an additional element: economic injury due to the unlawful practice. *See, e.g., Svenson v. Google Inc.*, 65 F. Supp. 3d 717, 730 (N.D. Cal. 2014); *Kwikset Corp. v. Superior Court*, 246 P.3d 877, 885-87 (Cal. 2011). And they offer no "patent-like protection." Nor do they replicate a "federal patent law cause of action" because they turn on the failure to follow statutory procedures, not a period of exclusivity for innovation.

Moreover, as discussed above and explained by Amgen (Br. 46-49), allowing an innovator to enforce the

mandatory BPCIA provisions through UCL claims would further Congress's intent of streamlining patent disputes in advance of product launch, not frustrate it. *See, e.g.*, *Ontiveros v. Zamora*, No. 08-cv-567, 2014 WL 3057506, at *3-4 (E.D. Cal. July 7, 2014) (finding no conflict preemption because UCL claim was consistent with "animating purpose and objectives" of federal law); *Aguayo v. Oldenkamp Trucking*, No. 04-cv-6279, 2005 WL 2436477, at *9-10 (E.D. Cal. Oct. 3, 2005) (same). And it would not require a court to answer any legal question that the BPCIA has delegated to an administrative agency. *Cf. Martinez v. Wells Fargo Home Mortg., Inc.*, 598 F.3d 549, 556 n.8 (9th Cir. 2010) ("regulation of a national bank's adherence to ... regulations is within the exclusive purview of" federal agency); *Snohomish Cty. v. Dynegy Power Mktg., Inc. (In re Cal. Wholesale Elec. Antitrust Litig.)*, 244 F. Supp. 2d 1072, 1078, 1083 (S.D. Cal. 2003) ("Plaintiff's state-law claims ... would inevitably conflict with [federal agency's] exclusive jurisdiction ...."), *aff'd sub nom. Pub. Util. Dist. No. 1 of Snohomish Cty. v. Dynegy Power Mktg., Inc.*, 384 F.3d 756 (9th Cir. 2004). Nor could Sandoz's exclusive-remedy argument establish the necessary conflict for all the reasons discussed above. *See supra* at 22-23.

In sum, there is no basis to find that Amgen's UCL claim is preempted by the BPCIA, which may explain why Sandoz never argued otherwise. The BPCIA does not meet the "high threshold [that] must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act." *Chamber of Commerce of the United States v. Whiting*, 563 U.S. 582, 607 (2011) (citations omitted).

* * *

Because the federal private right of action framework is entirely misplaced here, and because Sandoz has never argued that Amgen's state-law claims are preempted, this Court could and should resolve this case without deciding how a reference product sponsor can enforce the BPCIA's mandatory commands. That is, the Court should hold that Sections 262(*l*)(2)(A) and 262(*l*)(8)(A) are mandatory and that notice of commercial marketing must be given after FDA licensure (as Amgen argues), and remand for the Federal Circuit to determine the proper disposition of the actual claims before it (*i.e.*, California state-law claims) in light of Sandoz's waiver of any preemption argument and the fact that the relief initially requested is now moot.

As a practical matter, the critical point is this: if this Court holds that biosimilar applicants must follow the notice-and-exchange procedures and must give notice of commercial marketing after FDA licensure, that is (presumably) what biosimilar applicants will do—if there is at least the possibility of *some* enforcement mechanism. If a biosimilar applicant nonetheless chooses to completely disregard this Court's holding and flagrantly violate the law, a court can then decide the appropriate enforcement mechanism.

CONCLUSION

The decision of the Federal Circuit should be affirmed in part (as to its finding that the 180-day notice provision is mandatory and must be provided after licensure), reversed in part (as to its finding that the patent-exchange process is optional), and remanded.

Respectfully submitted,

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March 17, 2017

ADDENDUM

ADDENDUM A

	Sandoz's Biosimilar of Neupogen[i]	Celltrion's Biosimilar of Remicade[ii]	Apotex's Biosimilar of Neulasta[iii]	Apotex's Biosimilar of Neupogen[iv]	Hospira's Biosimilar of Epogen[v]	Amgen's Biosimilar of Humira[vi]
aBLA filed	05/08/14	08/08/14	10/16/14	12/12/14	12/16/14	11/25/15
aBLA provided	N/A	~10/27/14	12/31/14	03/04/15	03/03/15	02/10/16
Phase One Complaint	10/24/14[vii]	03/06/15	08/06/15	10/02/15	09/18/15	08/04/16
FDA approval	03/06/15	04/05/16	N/A	N/A	N/A	09/23/16
Notice of Comm. Marketing	07/08/14 & 03/06/15	02/05/15[viii]	04/17/15	04/17/15	04/08/15	N/A
Launch	09/03/15	11/28/16	N/A	N/A	N/A	N/A

[i] *See* Compl. ¶¶ 63, 69, *Amgen Inc. v. Sandoz Inc.*, No. 3:14-cv-04741 (N.D. Cal. Oct. 24, 2014); *see also* Sandoz Br. 18-26; License Approval, U.S. FDA, BLA 125553 (Mar. 6, 2015), http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/125553Orig1s000ltr.pdf.

[ii] Compl. ¶¶ 89, 123, *Janssen Biotech Inc. v. Celltrion Healthcare Co., Ltd.*, No. 1:15-cv-10698-MLW (D. Mass. Mar. 6, 2015), ECF No. 1; Answer ¶¶ 87, 104, ECF No. 39; Reply in Supp. of Appellants' Mot. to Extend Time for Filing Their Appeal Br. at 3, *Janssen Biotech Inc. v. Celltrion Healthcare Co.*, No. 17-1120 (Fed. Cir. Dec. 7, 2016); Press Announcement, U.S. FDA, *FDA approves Inflectra, a biosimilar to Remicade* (Apr. 5, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm494227.htm.

[iii] Compl., *Amgen Inc. v. Apotex Inc.*, No. 0:15-cv-61631 (S.D. Fla. Aug. 6, 2015), *consolidated with Amgen Inc. v. Apotex, Inc.*, No. 0:15-cv-62081 (S.D. Fla. Oct. 2, 2015), ECF No. 1; Answer ¶¶ 12, 52, Counterclaims ¶¶ 25, 65, ECF No. 35.

[iv] Compl. ¶ 51, *Amgen Inc. v. Apotex Inc.*, No. 0:15-cv-62081 (S.D. Fla. Oct. 2, 2015), ECF No. 1, *consolidated with Amgen Inc. v. Apotex Inc.*, No. 0:15-cv-61631 (S.D. Fla. Aug. 6, 2015); Consolidated Answer ¶ 12, Counterclaim ¶¶ 28, 81, ECF No. 64.

[v] Compl. ¶¶ 37, 43, 62, *Amgen Inc. v. Hospira, Inc.*, No. 1:15-cv-839 (D. Del. Sept. 18, 2015), ECF No. 1; Press Release, Hospira, Inc., *Hospira Submits New Biologics License Application to U.S. FDA for Proposed Epoetin Alfa Biosimilar* (Jan. 12, 2015), http://www.prnewswire.com/news-releases/hospira-submits-new-biologics-license-application-to-us-fda-for-proposed-epoetin-alfa-biosimilar-300018991.html.

[vi] Compl. ¶¶ 36, 38, *AbbVie Inc. v. Amgen Inc.*, No. 1:16-cv-666 (D. Del. Aug. 4, 2016), ECF No. 1; Answer ¶ 15, ECF No. 13; Press Announcement, U.S. FDA, *FDA approves Amjevita, a biosimilar to Humira* (Sept. 23, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm522243.htm.

[vii] Note that because Sandoz did not engage in the notice-and-exchange process at all, this was not a phase-one complaint but rather a suit based on state-law claims and a claim for patent infringement under 35 U.S.C. § 271(e)(2)(C)(ii).

[viii] Celltrion's marketing partner Hospira also claimed that commercial-marketing notice was given on March 31, 2014 (prior to the filing of the aBLA), when Celltrion filed a declaratory judgment action against Janssen for patent invalidity. *See* Opp. to Mot. to Dismiss at 22, *Hospira, Inc. v. Janssen Biotech, Inc.*, No. 14-cv-7049 (S.D.N.Y. Oct. 16, 2014), ECF No. 42 (citing Compl. ¶¶ 61, 62, *Celltrion Healthcare Co., Ltd. v. Janssen Biotech, Inc.*, No. 1:14-cv-11613 (D. Mass. Mar. 31, 2014)).

FILED
FEB 17 2017
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 15-1039

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC., ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* ADELLO BIOLOGICS, LLC IN SUPPORT OF PETITIONER

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February 17, 2017

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

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QUESTION PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was intended (a) to help speed biosimilars to market, while (b) assuring the reference biologic product a legislatively-prescribed 12 year period of exclusivity before the biosimilar is commercially sold. It provides a mechanism to allow potential patent disputes to be addressed before any commercial sale of the biosimilar. As part of this dispute resolution mechanism, § 262(*l*)(8)(A) of the BPCIA, the "notice provision", states that a biosimilar applicant shall provide notice to the reference sponsor of the biological product "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

Can a subsection (k) applicant provide its §262(*l*)(8)(A) notice before the biological product is licensed, or must the applicant await approval of the license, thereby effectively extending the exclusivity period provided by the BPCIA from the specified 12 years to 12.5 years?

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STATEMENT OF INTEREST OF THE *AMICUS CURIAE*[1]

Adello Biologics, LLC ("Adello") is a company that produces biologic products and brings them to market.

According to the U.S. Food and Drug Administration ("FDA"), biologics are "isolated from a variety of natural sources – human, animal, or microorganism – and may be produced by biotechnology methods and other cutting-edge technologies."[2]

The Patient Protection and Affordable Care Act ("Affordable Care Act") amends the Public Health Service Act ("PHS Act") to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to an FDA-licensed

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[1] Pursuant to Supreme Court Rule 37.3, Adello Biologics, LLC, through counsel, has timely notified the parties of its intent to file an *amicus curiae* brief and the parties have consented. Pursuant to Rule 37.6, undersigned counsel also certify that: (1) no counsel for a party authored this brief in whole or in part; (2) no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and (3) no person or entity – other than *amicus curiae*, its members, and its counsel – contributed money intended to fund the preparation or submission of this brief.

[2] U.S. Food and Drug Administration, "What is a biological product?", http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm.

biological product.[3] This pathway is provided in the part of the Affordable Care Act known as the Biologics Price Competition and Innovation Act ("BPCIA").

According to FDA, a biosimilar is "a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product." *Id.* The BPCIA allows for the filing of an abbreviated biologics licensure application ("aBLA") for biosimilars, and allows the aBLA to rely on the reference product's licensure. Given this streamlined pathway to approval, biosimilars cost less than the reference biologic product to which they are "similar."

Adello has a pipeline of biosimilar products to be submitted for licensure under the BPCIA. Adello is committed to providing patients access to biosimilars in a timely and affordable manner. Thus, the proper interpretation of the BPCIA has a significant impact on the ability of Adello, and indeed the biosimilar industry, to promptly bring biosimilars to the public.

If left uncorrected, the Federal Circuit's reading of Section 262(*l*)(8)(A) — to require that a product actually be licensed before notice of the date of first commercial marketing can be given — will

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[3]U.S. Food and Drug Administration, "Information on Biosimilars",www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ Biosimilars/.

needlessly delay the availability of biosimilars for at least six months longer than intended by Congress. Pharmaceutical companies, such as *amicus*, will bear the financial consequences of this additional delay in bringing their products to market, and therefore have an interest in ensuring that §262(*l*)(8)(A) is properly interpreted and applied. The consequences of an additional 180-day delay in the introduction of biosimilar-products will also be felt by patients, who would benefit from biologic therapies being made available sooner at lower cost, and by health care payers (including the Federal Government as a payer) and taxpayers who would bear the burden of higher Medicare and Medicaid costs resulting from a six-month delay in bringing lower-cost biosimilars to market.

INTRODUCTION AND BACKGROUND

As explained by FDA, biologics "often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available."[4] However, these "cutting-edge" and life-saving therapies frequently come at an exorbitant cost to patients "often exceeding tens of thousands of dollars per year."[5] [6]

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[4] U.S. Food and Drug Administration, "What is a biological product?, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm.

[5] Federal Trade Commission, *Follow-On Biologics Workshop*, Tr. 8 (Feb. 4, 2014) (statement of FTC Chairwoman Edith Ramirez); and Steven Kozlowski et al., *Developing the Nation's*

(continued...)

While biosimilars are, by definition "similar" to their reference biologic, they are not necessarily identical to it. Biologic molecules are very large, and it is difficult to provide an exact copy. Accordingly, development of a biosimilar version of a biologic is still expensive and time consuming — much more expensive and time consuming than, for example, the development of a generic version of a typical small-molecule drug. As Sandoz noted, an FTC report estimates that biosimilars are "likely to take eight to ten years to develop, and their development will likely cost between $100 and $200 million" — in contrast to the three to five years and $1 to $5 million it typically costs to develop a generic version of most small molecule drugs.[7]

(continued...)
Biosimilars Program, 365 New Eng. J. Med. 385, 385 (Aug. 4, 2011) http://www.nejm.org/doi/pdf/10.1056/NEJMp110728.

[6] Third party data collection company QuintilesIMS reports that Neupogen's estimated sales totaled about $397,000,000 in the six months prior to the launch of Zarxio (Sandoz's biosimilar product). National Sales Perspectives, Neupogen, February 13, 2017, *available at* IMS Smart MVP Solutions, https://websolutions.imshealth.com/EB2/User/Validate_UserID.aspx?TARGET=SMhttp://customerportal.imshealth.com/portal/site/imsportal. The six month revenue from sales for this single product provides a strong indication of the significance of postponing competition by delaying the commercial marketing of biosimilar drugs for an additional six months.

[7] Pet. at 2, *citing* FTC Report, *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, iii (June 2009) [hereinafter *FTC Report*], https:// www.ftc.gov/sites/default/files/ documents/reports/ emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

Despite these costs, biosimilars save money.[8] The record before Congress showed that more competition in the biologics market could save government and private payers tens of billions of dollars.[9] To this end, Congress wanted to bring biosimilar drugs to market quickly. In order to do this, Congress proposed a mechanism designed to swiftly and efficiently deal with the expected patent litigation initiated against the biosimilar developer that could otherwise delay the public's access to biosimilars for much longer. The BPCIA represents an effort to create a balance between promoting innovation and competition while addressing potential delays in biosimilars reaching the market.

That balance is explicit in the BPCIA. The BPCIA prohibits FDA from making its approval of the aBLA effective earlier than 12 years after the first licensing of the reference product. 42 U.S.C. § 262(k)(7)(A), which guarantees the reference product 12 years of exclusivity. At the same time, the BPCIA seeks to expedite the introduction of biosimilars by the conclusion of the exclusivity period.

There are three major hurdles involved in bringing a biosimilar to market: (1) obtaining approval from FDA; (2) the 12 years of marketing

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[8] Pet. at 2 ("When Congress passed the BPCIA, purchases of biologics represented 21% of the $307 billion spent annually on medicines, and spending on biologics was increasing materially". CA JA A389-A391).

[9] *E.g.*, Judith A. Johnson, Cong. Research Serv., RL34045, FDA Regulation of Follow-On Biologics 4 (2010).

exclusivity given to the reference biologic product's sponsor ("RPS") which prevents FDA from licensing any biosimilar until that time period is up (42 U.S.C. § 262(k)(7)(A)); and (3) navigating patents and patent litigation. Thus, while actual FDA approval is critical to bringing a biosimilar to market, the 12-year non-patent exclusivity and potentially various patents imparting their own exclusivity are equally important when launching a biosimilar.

To further the overriding goal of bringing biosimilars to market quickly once the 12 years of exclusivity have run, the BPCIA provides a central mechanism for the early resolution of patent claims by establishing an "artificial" patent-infringement claim. 35 U.S.C. § 271(e)(2)(C)(ii). This artificial infringement claim may be litigated while FDA is still reviewing the aBLA and prior to its approval.

As described by the Acting Solicitor General, section 262(*l*) sets out this process in four phases. See 42 U.S.C. §§ 262(*l*)(2)-(8). *See* United States Br. 4-7.

(1) In the Information phase, the applicant for the aBLA ("subsection (k) applicant") "shall provide" the RPS with a copy of both the aBLA and manufacturing-process information. 42 U.S.C. § 262(*l*)(2)(A). If the subsection (k) applicant does not comply and timely provide this information, the subsection (k) applicant's submission of its aBLA is deemed an artificial act of infringement. 35 U.S.C. § 271(e)(2)(C)(ii).

(2) In the Comprehensive List Phase, the RPS and applicant produce a list of the patents on which infringement claims could reasonably be asserted. 42 U.S.C. § 262(*l*)(3). The subsection

(k) applicant's submission of its aBLA is an artificial act of infringement "with respect to a patent that is identified in the list of patents described in section [262](*l*)(3)," i.e., in the Comprehensive List. 35 U.S.C. § 271(e)(2)(C)(i).

(3) In the Round 1 Litigation Phase, the subsection (k) applicant and the RPS identify patents for Round 1 Litigation. 42 U.S.C. §§ 262(*l*)(4)-(6). The RPS then "shall bring an action for patent infringement" for each patent on the Round 1 lists within 30 days. *Id.* If the subsection (k) applicant and RPS successfully complete these steps, then the Round 1 litigation will be filed about 250 days or less after FDA accepts the aBLA for review. *Id.* §§ 262(*l*)(2)-(6).

(4) The Round 2 Litigation Phase addresses the patents on the Comprehensive List not addressed in Round 1. *Id.* §§ 262(*l*)(8)(B)(i) and (ii) (remaining patents). If the subsection (k) applicant has timely provided the RPS with the information required in the Information Phase, neither the RPS nor the subsection (k) applicant may bring a declaratory-judgment action based on a Round 2 patent before the subsection (k) applicant provides advance notice of the first commercial marketing of its biosimilar. *Id.* § 262(*l*)(9)(A).

Section 262(*l*)(8)(A) ("the notice provision"), at issue here, governs the timing of that notice. It provides that the "applicant shall provide notice" to the RPS "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [Section 262](k)." *Id.* § 262(*l*)(8)(A).

One further clarification of the statutory procedure is appropriate here. FDA approval of a biosimilar product does not create an immediately operative license to market the biosimilar product. The application for licensure (the aBLA) can, of course, be submitted by the subsection (k) applicant during the term of the reference product's period of exclusivity. FDA then reviews (and hopefully approves) the biosimilar's aBLA – during the exclusivity period. However, FDA approval does *not* confer an immediately operative license to commercially market the biosimilar product. The approved license cannot be made *effective* until the 12-year exclusivity period has expired. 42 U.S.C. § 262(k)(7)(A).

SUMMARY OF ARGUMENT

The BPCIA was intended by Congress to speed biosimilars to market, while preserving incentives for innovation by providing a 12 year period of exclusivity — a balance that is disrupted by the Federal Circuit's ruling. The Federal Circuit's reading of §262(*l*)(8)(A) of the BPCIA ignores the plain language of the statute, as well as Congress's intent in drafting it.

Congress provided 12 years of market exclusivity to the RPS. 42 U.S.C. § 262(k)(7)(A). By holding that the notice cannot be given until the biosimilar product has been licensed, the Federal Circuit decision impermissibly converts this statutory 12-year exclusivity period into a 12.5-year period. Under the Federal Circuit's erroneous reading, the notice given by a subsection (k) applicant under § 262(k)(7)(A) would extend the 12-

year period of exclusivity by 180 additional days, every time.

The notice provision is explicit in stating that an *applicant* can give notice – negating any suggestion that only a subsection (k) applicant whose application has been approved can do so. If Congress wished to allow notice to be given only after FDA had approved the application, it would have required the "holder" – meaning a subsection (k) applicant whose application had been approved – to provide the notice. The notice provision's reference to the notice being provided with respect to the date of commercial marketing of the "licensed" product should not be read to mean that notice can be given only for a previously-licensed biosimilar product. To the contrary, it refers to the elementary fact that at the time of commercial marketing, the product will necessarily be licensed.

ARGUMENT

I. A Subsection (K) Applicant May Give Notice Prior To FDA Licensure Of The Biosimilar Product

The Federal Circuit concluded that a subsection (k) applicant cannot provide the 180-day notice of first commercial marketing of its biosimilar pursuant to § 262(*l*)(8)(A) until after FDA licensure of the biosimilar product. *Amicus* agrees with Petitioner that the Federal Circuit erred in this interpretation of §262(*l*)(8)(A). The subsection (k) applicant may provide notice of commercial marketing – and thus trigger the 180 day period — prior to FDA licensure. That understanding is consistent with both the text of § 262(*l*)(8)(A), and the broader purposes of the BPCIA to allow the

biosimilar product to expeditiously reach market, while allowing the reference product a 12 year exclusivity period and fair notice and opportunity to assert any patent rights it might have. Thus, the subsection (k) applicant may give notice of first commercial marketing before FDA approves the aBLA application. Indeed, if subsection (k) applicants must wait until FDA licenses the biosimilar product before giving notice, the 12 year period of exclusivity at the heart of the statute would always be converted to 12.5 years.

A. Section 262(*l*)(8)(A) Allows the 180-Day Notice to be Given "not later than 180 days before the date of commercial marketing," Regardless of the Date of FDA Licensure

The notice provision at issue is designed to provide a 180-day time period during which the RPS can consider whether to assert, and in fact assert, its rights prior to the commercial marketing of the reference product. It provides that:

> [t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

42 U.S.C. § 262(*l*)(8)(A). A plain reading of that section indicates that notice should be given not *later* than 180 days before the date of the first commercial marketing, and a commonsense reading indicates that the notice can be given at any time before, provided that it is given by a subsection (k) applicant. That is clear enough from the fact that the benchmark date is the date of "first commercial

marketing." The BPCIA is quite clear about when the earliest date of first commercial marketing may be: 12 years after the date the reference product was approved, *i.e.*, at the end of the 12-year period of exclusivity and no longer.

The statute certainly does not say that notice can only be given 180 days after FDA licensure of the biosimilar product, nor does the statute use the date when the biosimilar product is licensed as the benchmark for that notice. To the contrary, the statutory reference to the product being licensed is simply part of specifying the actual benchmark: Q. What is it that is being first commercially marketed at that time? The answer is "the biological product licensed under subsection (k)."

If the Federal Circuit were correct, the requirement that the product must be licensed before the notice is given would be an important precondition to that notice. But it is extremely unlikely that Congress would bury such an important precondition to giving notice as part of an adjectival phrase.

There is nothing illogical in the understanding that notice of the "date of the first commercial marketing of the biological product licensed under subsection (k)" can be provided before the license has been issued. The Federal Circuit itself did not suggest that it would be an unreasonable or ungrammatical reading of the notice provision. To the contrary, "licensed" as used in the statute is not a precondition to giving notice, but instead simply and accurately describes what the product will be at the "date of its first commercial marketing." 42 U.S.C. § 262(*l*)(8)(A). The date of first commercial

marketing can only be of a licensed product. The biosimilar product cannot be marketed until FDA licenses it. Therefore, the reference to the licensed product makes perfect sense in the notice provision.

The Federal Circuit's alternative reading would not permit a mere subsection (k) applicant, who has not yet received approval of its application, to give notice. That reading, however, conflicts with the specific words of the notice provision; Section 262(*l*)(8)(A) expressly authorizes a "subsection (k) applicant" to provide notice. *Id.* The notice provision thus contemplates that the notifying party need only have requested FDA approval; *i.e.*, that the notifying party be a subsection (k) *applicant*.

Indeed, if Congress intended to allow notice to be given only by someone who was already permitted to market, or who had their application approved, then Congress would have said so. Elsewhere in the same statute, Congress refers to parties who have had their application approved as "holders." *E.g. id.* § 262(m)(3) (referring to "the holder of an approved application"). If Congress had meant to require approval before the notice is given, it would have used consistent language and called the notifying party in §262(*l*)(8)(A) "the holder of an approved application."

Crucial here is the fact that FDA approval of a biosimilar product does not automatically create an operative license to market the biosimilar product. This is because the approval itself is not effective, and one cannot fairly say that the biosimilar product has been licensed, until the 12-year period has expired. The statute is explicit on this point:

> [a]pproval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

Id. § 262(k)(7)(A).

Thus, the approved license becomes effective only after the expiry of the 12 year exclusivity period. Prior to the approved license becoming effective, the biosimilar cannot be marketed.

Congress appears to have chosen its language carefully in allowing a subsection (k) applicant to give notice. Use of the term "applicant" is broad enough to encompass all of the following: a mere applicant; someone who was an applicant and who is now a "holder" of an approved license; and someone who already has an operative license made effective by FDA upon the expiration of the 12-year exclusivity period. All three circumstances are included within the term "applicant". If Congress had intended another, for example more limited meaning, it would have used the word "holder", or "licensee", which would have excluded mere applicants from giving notice.

The Federal Circuit's alternative interpretation is based on its elevation of the word "licensed" in the adjectival phrase into a full-scale limitation on when notice must be provided. In so holding, the Federal Circuit appeared to recognize that if its construction of the notice provision converted §262(k)(7)(A)'s 12-year period of exclusivity into a 12.5-year period (12 years, plus 180 days for notice), that would create a "conflict" that would counsel against such a construction. Pet. App. 22a. The 12 year exclusivity

period is at the core of the statute. The Federal Circuit ultimately dismissed that concern by suggesting that this would not happen in the "usual case," *id.*, and the 12 year period would be converted to 12.5 years only in some circumstances:

> [i]t is true that in this case, as we decide *infra*, Amgen will have an additional 180 days of market exclusion after Sandoz's effective notice date; that is because Sandoz only filed its aBLA 23 years after Amgen obtained FDA approval of its Neupogen product. Amgen had more than an "extra" 180 days, but that is apparently the way the law, business, and the science evolved. That extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products."

Id.

The Federal Circuit apparently conceived that the biosimilar product could, in fact, be licensed long before the 12-year exclusivity period had expired. Therefore, "in the usual case," notice could be provided and the 180 day period could run after license approval without extending the 12 year exclusivity period. The premise of that argument is that an application could be approved long before the 12-years expired, and thus the product would be licensed as soon as the agency gave its approval – before the end of the period of exclusivity.

But that view is demonstrably wrong under the statute. One can surely apply for a license before the 12 years have expired. And one can surely conceive that FDA might indicate its approval of that application before the 12 years have expired. But, as discussed above, the approval is not *effective*

and the biosimilar product is not actually licensed until the 12-year period has expired. 42 U.S.C. § 262(k)(7)(A).[10]

Thus, the actual result under the Federal Circuit's reading is that in *every* case, instead of a 12-year period of exclusivity, the period of exclusivity would be 12.5 years (or, for reference biologic products with approval dates more than 12 years prior to the passage of the BPCIA, at least an extra 6 months of exclusivity).[11] Given that

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[10] The Federal Circuit simply failed to comment on this provision specifying when approval becomes effective.

[11] It is conceivable that the Federal Circuit's erroneous reading of the notice provision would not only delay the market entry of a first biosimilar, but also could delay the ability of second and subsequent biosimilars from receiving a designation of interchangeability from FDA.

There is a subset of biosimilars known as "interchangeables" which, in addition to meeting the requirements of being "biosimilar" to a reference product, are so similar that they may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. 42 U.S.C. § 262(i)(3). The interchangeability determination is typically done by FDA after the approval as a biosimilar. Once FDA has determined that a first biosimilar is an interchangeable, it receives a period of exclusivity where it is the only interchangeable on the market. *Id.* § 262(k)(6). The shortest period of exclusivity for the first interchangeable provided by the statute is one year. *Id.* (FDA "shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of [262(k)(6)(A)-(C)]- (A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product...").

(continued...)

Congress's intent was to help speed biosimilars to market and clearly set a 12-year exclusivity period – points that no one disputes, and which reflect the overall tone and tenor of the statute – the Federal Circuit's reading leads to an inconsistent and unrealistic result. As the district court observed, "[h]ad Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so." Pet. App. 76a.

B. Notice Before Licensure Provides a Well-Crystalized Controversy

The Federal Circuit posited that its approach to the notice provision makes sense because "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystalized controversy regarding the need for injunctive relief." Pet. App. 21a. While striving for a more crystallized controversy is laudable, the Federal Circuit's position unreasonably elevates any hypothesized benefit at the expense of the BPCIA's language and more fundamental purposes. Indeed,

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(continued...)
Under the Federal Circuit's holding, if the first biosimilar has also been designated as an interchangeable by FDA, and is ready to market as an interchangeable as of the date of licensure – but is required to wait until the date of licensure before notifying the RPS – this first interchangeable's commercial marketing is delayed by 180 days. And, as an interchangeable meriting one year (or more) of being the only interchangeable on the market, this one year (or more) of exclusivity begins 180 days later than it otherwise would have, and the designation of a second biosimilar as interchangeable in the marketplace is thus delayed by one year plus 180 days.

waiting until after licensure to create a "crystallized controversy" for litigation is exactly what Congress intended to avoid by making the mere submission of an aBLA itself an "act of infringement." 35 U.S.C. § 271(e)(2)(C).

The Federal Circuit's theory is that a "crystallized controversy" does not exist until the biosimilar product, as well as its manufacturing and use, are licensed; *i.e.*, fixed and unchangeable. By this reasoning, all litigation which takes place before licensure is premature. And that logic conflicts with the Federal Circuit's own statements in the same opinion concerning the fundamental objective of the statute, which was to allow patent litigation to proceed even before licensure and commercial marketing. Pet. App. 6a. As the Federal Circuit explained, the "BPCIA amended the Patent Act to create an artificial 'act of infringement' and to allow infringement suits based on a biosimilar application prior to FDA approval and prior to the marketing of the biological product." *Id.*

The BPCIA expressly contemplates litigation before licensure, as it provides for a situation where all relevant patents can be placed in Round 1 litigation. See 42 U.S.C. §§ 262(*l*)(5)(B), and (6)(B), *supra* p. 7. If the parties follow the schedule in Section 262(*l*), Round 1 litigation will begin no later than about 250 days after FDA accepts the aBLA for review. See *id.* §§ 262(*l*)(2)-(6), *supra* p. 7.

Given that an aBLA may be submitted, and accepted by FDA for review, a full eight years before FDA could grant an effective license (*see* §§ 262(k)(7)(A) & (B)), it is clear that Congress intended that patent litigation on all relevant

patents could begin as early as about 7 years before the aBLA is approved by FDA (8 years less 250 days).

The Federal Circuit's expressed concern for crystallizing controversies for suit is even more unrealistic when one imagines a situation where there are no relevant patents to be placed at issue. This scenario is entirely possible, as patents may have expired by the time of licensure, or any patent disputes may have already been resolved between the parties. Yet, the 180-day windfall mandated by the Federal Circuit's reading would apply even in situations like these where the RPS has no infringement claim to "justify" the delay. Thus, the marketing of the biosimilar would be delayed for 180 days to protect a "fully crystalized controversy" that in fact would not exist.

C. The Federal Circuit's Interpretation Undermines the BPCIA's Overriding Purpose

The Federal Circuit's interpretation is squarely at odds with the broader purpose of the BPCIA in bringing biosimilar products to market as soon as possible.

Nowhere in the BPCIA is there evidence that Congress wanted biosimilar patent suits filed after licensure. If Congress had wanted that, the creation of the artificial act of infringement under Section 271(e)(2)(C), and the mechanism for patent resolution prior to licensing set forth in Section 262(*l*), would have been unnecessary. A way to resolve patent disputes after licensure already existed: a RPS could bring a declaratory judgment action and seek a preliminary injunction under the

Patent Act, including 35 U.S.C. § 271(a) and (g); *see MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

But Congress did not want that. Congress wanted to resolve patent disputes early. This desire led Congress to make the *submission* of an aBLA an artificial act of infringement in order to allow for litigation shortly after the aBLA submission. In fact, the aBLA may be submitted up to 8 years before FDA can license it, providing time to commence patent litigation as early as seven years before licensure. 42 U.S.C. §§ 262(k)(7)(A) and (B).

A practical application of the Federal Circuit's reading of the notice provision is helpful here. When the subsection (k) applicant and the RPS are engaging — or have engaged — in the patent exchange process of the Comprehensive List phase, only the agreed-upon patents may be litigated in Round 1 litigation. If the parties participate in the patent dispute mechanism of § 262(*l*), the litigation of any remaining patents in Round 2 is postponed by the BPCIA until notice is given. *Id.* § 262*(l)*(9)(A). Thus, it may be the 180-day notice that allows Round 2 litigation to commence. *Id.*

Yet, under the Federal Circuit's approach, in every situation where the parties participate in the patent dispute mechanism of § 262(*l*), any litigation on the Round 2 patents must wait until the biosimilar product is licensed and then until notice is given by the subsection (k) applicant.

The notice provision is thus properly viewed as providing the RPS an opportunity to bring suit on the Round 2 patents that it previously could not bring while the subsection (k) applicant was

following the litigation mechanism of Section 262(*l*) prior to the licensure of the biosimilar. The notice provision, rather than standing alone, assumes that the parties have already engaged in the preceding steps: The "entirety of (*l*)(8), including (*l*)(8)(A)'s notice provision, serves to ensure that an RPS will be able to assert all relevant patents before the (k) applicant launches its biosimilar product." Pet. App. 48a (Chen, J. dissenting).

CONCLUSION

The judgment of the Federal Circuit should be reversed.

Respectfully submitted,

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FILED
FEB 17 2017
OFFICE OF THE CLERK
SUPREME COURT, U.S.

Nos. 15-1039, 15-1195

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Cross-Petitioners,

v.

SANDOZ INC.,

Cross-Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER AND CROSS-RESPONDENT SANDOZ INC.

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February 17, 2017

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae America's Health Insurance Plans ("AHIP") files this brief in support of the petitioner and cross-respondent Sandoz Inc.

AHIP is the national trade association representing the health insurance community. It advocates for public policies that expand access to affordable healthcare coverage for all Americans through a competitive marketplace that fosters choice, quality and innovation. Along with its predecessors, AHIP has over 50 years of experience in the industry. AHIP's members provide health and supplemental benefits through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid. As a result, AHIP's members have broad experience working with hospitals, physicians, patients, employers, state governments, the federal government, pharmaceutical, biotechnology and device companies, and other healthcare stakeholders to ensure patients have access to needed treatments and medical services – including through robust price competition in prescription drug markets.

This case raises critical issues for health insurers concerning the proper interpretation of the 2010 Biosimilars Price Competition and Innovation Act

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[1]All parties have consented to the filing of this brief, and letters reflecting such consent accompany this brief. No counsel for a party authored this brief in whole or in part; no counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief; and no one other than *amicus*, its members, or its counsel made such a contribution.

("BPCIA"),[2] through which Congress created an expedited approval pathway for "biosimilars." Biosimilars are highly similar or interchangeable versions of U.S. Food and Drug Administration ("FDA")-licensed branded biologic medicines. (A brand biologic in this context is known as a "reference product" and its license holder as a "Reference Product Sponsor" or "RPS."). Congress enacted the BPCIA to increase competition in biologic markets by allowing for the expedited introduction of lower-cost biosimilars, thereby (1) accelerating patients' access to medicines that are among the most medically necessary and expensive drugs on the market today and (2) helping control spiraling health care costs, which are increasingly due to spending on prescription drugs – especially high-priced drugs like branded biologics. Health insurance plans (and the consumers they serve) are among the principal beneficiaries of the BPCIA's biosimilars approval regime.

Both statutory interpretation issues in this case implicate the BPCIA's overarching goal of expediting patients' access to affordable, lifesaving medicines.

The *first* issue is whether the Federal Circuit was correct in holding that the BPCIA's 180-day notice of commercial marketing provision should be read to delay patients' access to biosimilars for *six additional months beyond the statute's express 12-year market exclusivity period for reference products*. AHIP agrees with Sandoz that the Federal Circuit's interpretation

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[2] Patient Protection & Affordable Care Act, Pub. L. No. 111-48, §§ 7001-03, 124 Stat. 119, 804-21 (2010).

of the notice provision was *incorrect* and if upheld would impose significant, unintended costs on the U.S. healthcare system and consumers.

The *second* issue is whether the Federal Circuit was correct in holding that a biosimilar applicant is not required to share its application with the RPS to initiate the BPCIA's patent dispute resolution process – known as the "patent dance." AHIP agrees with Sandoz that the Federal Circuit's interpretation of the application-sharing provision was *correct*, that biosimilar applicants may forgo the patent dance if doing so affords a quicker, more efficient path to market, and that this reading of the statute squares with Congress's goal of speeding access to affordable lifesaving medicines.

AHIP and its members have a strong interest in ensuring that courts interpret the BPCIA consistent with Congress's overriding policy goal of ensuring competition and patients' access to biosimilars. Drug costs are a significant driver of premiums and out-of-pocket costs for consumers, and biologic costs are in turn a significant driver of rising drug costs. A robust biosimilar system is vital to patients' ability to access these important treatments and to relief for consumers, employers, and government health insurance programs from unrelenting drug cost increases. Proper resolution of the issues in this case is critical to implementing Congress's intent in enacting the BPCIA and to health insurance plans' ability to provide consumers with quality coverage at premiums that are affordable.

STATEMENT

A. The Role of Prescription Drug Costs in the Upward Spiral of Health Care Spending.

Prescription drug costs in the United States are increasing at an unsustainable rate. U.S. spending on prescription drugs, including biologics, jumped 12.6 percent to $424 billion in 2014, and "drug spending growth is estimated to have remained elevated in 2015." Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Observations on Trends in Prescription Drug Spending* 3, Table 1 (Mar. 8, 2016) ("2016 ASPE Report").[3] In 2015, Spending for drugs covered under the Medicare Part B program (which include outpatient prescription drugs, such as biologics, that are administered by physicians rather than by patients themselves) totaled $24.6 billion, a 14 percent increase from 2014. Ctrs. for Medicare and Medicaid Servs. ("CMS"), *Medicare Drug Spending Dashboard* Table 1b (Nov. 14, 2016).[4] Likewise, 2015 spending for drugs, including biologics, in the Medicare Part D prescription drug program increased by 13 percent from 2014, to $138 billion. *Id.*, Table 1a. Drug spending as part of the Medicaid program increased by 24 percent from 2013 to 2014. Medicaid and CHIP Payment and Access Commission

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[3]https://aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf.

[4]http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-11-14.html.

(MACPAC), *Report to Congress on Medicaid and CHIP* 14 (June 2016).[5]

Spending on prescription drugs, including biologics, has also increased as a share of overall health care costs. According to the Department of Health and Human Services, drug spending rose from 7 percent of total health care spending in the 1990s to 15.3 percent of spending in 2013 and is expected to further rise to 16.8 percent of total health care spending by 2018. 2016 ASPE Report 3. The drug spending growth rate has exceeded rates of spending growth in other health care sectors: For example, prescription drug spending in 2014 grew by 9 percent, compared to the 6.3 percent growth rate for physician and clinical services and the 5.6 percent growth rate for hospital expenditures for that year. Ctrs. for Medicare and Medicaid Servs., *NHE Fact Sheet* (last modified Dec. 2, 2016).[6] Moreover, the CMS data only includes retail prescription drug spending, thus excluding medicines administered in hospital settings, which are typically among the most expensive drugs.

Higher prescription drug prices have a direct impact on insurance premiums, thereby hurting consumers. One analysis modeled the impact of a hypothetical specialty drug (a category that includes most biologics) costing $100,000 per treated patient that would increase total health care costs by $250 for

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[5]https://www.macpac.gov/wp-content/uploads/2016/06/June-2016-Report-to-Congress-on-Medicaid-and-CHIP.pdf.

[6]https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html.

every 0.25 percent of the population using the drug. Because underlying health costs are the basis for setting insurance premiums, under this model, a specialty drug used by just 5 percent of the population would lead to an almost 15 percent increase in premiums. Bradford R. Hirsch, Suresh Balu & Kevin A. Schulman, *The Impact of Specialty Pharmaceuticals As Drivers Of Health Care Costs*, Health Affairs 33, No. 10, 1714-20 (2014).

In short, increased prescription drug spending has been a significant driver of rising healthcare costs overall. Prescription drug spending is also a significant driver of *consumer* healthcare costs, both through direct out-of-pocket spending and through contributions to premiums. Consumers – as well as hospitals, providers, employers, and state Medicaid directors – have expressed increasing frustration regarding drug costs that show no signs of slowing down.

Health insurance plans have used a number of solutions to help mitigate the impact of high drug costs on patients, businesses that offer their employees health care coverage, and taxpayers who fund government healthcare programs such as Medicare Parts B and D. In particular, they have encouraged the use of less expensive but equally safe and effective generic versions of brand-name small-molecule drugs – for example, through tiered formularies (*i.e.*, lists of covered drugs) in which consumers have lower cost-sharing obligations when they use generic drugs. Congress created an expedited approval pathway for small-molecule generic drugs in 1984 when it passed the Hatch-Waxman amendments

to the Food, Drug and Cosmetic Act. Thanks to the availability, prescribing, and dispensing of lower-cost generic drugs, the U.S. healthcare system saved $227 billion between 2005 and 2015. IMS Health and Generic Pharm. Ass'n, *2016 Generic Drug Savings and Access Report* 5 (8th ed. 2016).[7] Indeed, the use of generic drugs has become pervasive, to the great benefit of consumers of health insurance, making up 89 percent of prescriptions dispensed but only 27 percent of total medicine spending. *Id.*

B. The Promise of Biosimilars and the BPCIA.

Biosimilars represent the next frontier in the fight against rising drug costs. Biologics, unlike the relatively simple small-molecule drugs covered under Hatch-Waxman, are complex, large-molecule medicines derived from living organisms and are used to treat a range of conditions, including rheumatoid arthritis, plaque psoriasis, Crohn's disease, lymphoma, leukemia, breast cancer, and diabetes. Biologics are among the most expensive drug products in the United States and account for an ever increasing share of U.S. prescription drug costs. Federal Trade Comm'n, Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposal on Competition, 78 Fed. Reg. 68,840 (Nov. 15, 2013) (noting that biologics are "among the most important pharmaceutical products in the United States" and "comprise the fastest growing sector within pharmaceuticals."). In 2010, spending on biologics in the United States was $67

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[7]http://www.gphaonline.org/media/generic-drug-savings-2016/index.html

billion, or approximately 20 percent of overall drug spending. IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2010* 4, 6 (Apr. 2011).[8] By 2013, spending on biologics in the United States had increased nearly 40 percent to $92 billion, or approximately 28 percent (also a 40 percent increase) of overall drug spending. Alex Brill, *The Economic Viability of a U.S. Biosimilars Industry*, Matrix Global Advisors 4 (Feb. 2015).[9] *See also* 2016 ASPE Report 6-7 (noting that spending on "specialty drugs," which include biologics, rose from $14.5 billion in 2009 to $27.1 billion in 2015 – an annual average growth rate of 11 percent); *id.* 7 (spending on specialty drugs as a percentage of spending on all retail drugs increased from 5.7 percent to 7.6 percent – a 33.3 percent increase – between 2009-2014). Nine of the 10 top selling drugs in the world are biologics. Evaluate Grp., *EP Vantage 2017 Preview* 5 (Dec. 2016) ("*Evaluate Report*").[10]

On average, biologics cost $45 per day, compared to $2 per day for small-molecule drugs. Steve Pociask, *Lifesaving Drugs at Lower Costs*, Am. Consumer Inst. Ctr. for Citizen Research ConsumerGram 2 (July 22, 2014).[11] Some biologics cost tens or even hundreds of

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[8]https://www.imshealth.com/files/web/IMSH%20Institute/Reports/The%20Use%20of%20Medicines%20in%20the%20United%20States%202010/Use_of_Meds_in_the_U.S._Review_of_2010.pdf.

[9]http://www.matrixglobaladvisors.com/storage/MGA_biosimilars_2015_web.pdf.

[10]info.evaluategroup.com/rs/607-YGS-364/images/EPV2017Prev.pdf.

[11]http://www.theamericanconsumer.org/2014/07/new-consumergram-lifesaving-drugs-at-lower-costs/.

thousands of dollars per patient per year. Humira® (adalimumab), which treats rheumatoid arthritis and other conditions and is the top selling drug in the world (approximately $17.6 billion projected sales in 2017 (*Evaluate Report* 5)), costs over $50,000/year. Judith A. Johnson, *FDA Regulation of Follow-On Biologics*, Cong. Research Serv., RL34045, 1 (Apr. 26, 2010) ("CRS Report"). The discounted price of a two-week dose of Humira® in 2009 was $630; by 2015, it had more than doubled, to $1,331. Robert Langreth, Michael Keller & Christopher Cannon, *Decoding BigPharma's Secret Drug Pricing Practices*, Bloomberg 3 (June 29, 2016).[12] Cerezyme® (imiglucerase), which treats Gaucher's Disease, costs $200,000/year. Erwin A. Blackstone & Joseph P. Fuhr, *Innovation and Competition: Will Biosimilars Succeed?*, Biotechnology Healthcare 24-27 (Spring 2012).[13] In 2014, Medicare Part B spent $1.5 billion for the non-Hodgkins lymphoma biologic Rituxan® (rituximab), an increase of nearly 25 percent since 2010. Ctrs. for Medicare and Medicaid Servs., *Medicare Drug Spending Dashboard* (Dec. 21, 2015) Chart 1b.[14] Many biologics have been on the market for a decade or more without any competition. Congress sought to address this issue through the BPCIA.

The BPCIA's expedited approval pathway allows FDA to approve a biosimilar based on the agency's previous findings of safety and efficacy for the RPS.

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[12]https://www.bloomberg.com/graphics/2016-drug-prices/.

[13]http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3351893/.

[14]http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-12-21.html.

This pathway, like the analogous though different Hatch-Waxman pathway for small-molecule generic drugs, serves the dual purposes of (1) reducing biosimilars' development costs; and (2) facilitating quicker FDA review, thus expediting competition and consumer access to affordable versions of life-saving medicines.

Increased competition from biosimilars holds the potential for enormous savings for the U.S. healthcare system, with one study estimating reductions in direct spending on biologics of more than $44 billion from 2014-2024. Andrew Mulcahy, Zach Pretmore & Soren Mattke, *The Cost Savings Potential of Biosimilar Drugs in the United States*, RAND Corp. (2014).[15] In Europe, where biosimilars have been marketed since 2004, projected savings from biosimilars through 2020 for three particular product classes have been estimated between €11.8 and €33.4 billion. Robert Haustein, et al., *Saving Money in the European healthcare systems with biosimilars*, 1(3-4) Generics & Biosimilars Initiative J. 120-26 (2012)[16] Other savings estimates are even more optimistic, with one large pharmacy benefit manager with extensive experience and data on biologics concluding that biosimilar versions of 11 high-priced biologics would save the U.S. healthcare system $250 billion from 2014-2024.

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[15]http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

[16]http://gabi-journal.net/saving-money-in-the-european-healthcare-systems-with-biosimilars.html.

Express Scripts, *The $250 Billion Potential of Biosimilars* (Apr. 23, 2013).[17]

Given the growing role of biologics in overall drug spending and the potential savings to the U.S. health care system and patients from biosimilars, the need for a robust biosimilar system cannot be overstated. The savings made possible by biosimilars lower premiums and out-of-pocket costs to consumers of insurance, thereby increasing access to lifesaving biologic medicines. Congress recognized all this and enacted the BPCIA to be a critical part of efforts by the health insurance industry and other stakeholders to stem the tide of spiraling health care costs that threatens to overwhelm our economy and jeopardize the public health in the 21st century.

SUMMARY OF ARGUMENT

The BPCIA's Notice of Commercial Marketing Provision.

The Federal Circuit's reading of the BPCIA's notice of commercial marketing provision (42 U.S.C. § 262(l)(8)) undermines Congress's intent and policy objectives, at enormous cost to our healthcare system. The Federal Circuit's holding that a biosimilar applicant can only give effective notice *after* FDA licenses the biosimilar effectively extends the BPCIA's express 12-year RPS exclusivity period to 12 years *and six months*. This "extra-statutory exclusivity windfall" (Pet. App. 43a-44a (Chen, J., dissenting)) rewrites the BPCIA's careful compromise between

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[17]http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars.html.

competition and innovation by delaying patients' access to more affordable, life-saving medicines for six months more than Congress expressly provided. The Federal Circuit's erroneous interpretation of the notice provisions would, if upheld, increase healthcare costs for patients, businesses providing health insurance for their employees, and insurers in a manner and to a degree that Congress did not intend. For example, one report estimates that the six-month delay in the availability of the biosimilar at issue in this case, Sandoz's Zarxio® (filgrastim), cost the U.S. healthcare system $270 million ($45 million per month).

The BPCIA's Application-Sharing Provision.

The Federal Circuit correctly held that 42 U.S.C. § 262(l)(2)(A) does not require a biosimilar applicant to share its application with the RPS (or allow an RPS to force an applicant to provide this information through an automatic private injunction). The BPCIA sets forth specific consequences if an applicant declines to provide this information – consequences which do not include allowing the RPS to obtain a court order forcing the applicant to engage in the information exchange process. This holding squares with Congress's intent in the BPCIA to give applicants the choice of triggering the patent dance or foregoing that process – whichever the applicant thinks will most efficiently serve the statute's goal of swift public access to biosimilars.

ARGUMENT

I. THE FEDERAL CIRCUIT'S READING OF THE BPCIA'S NOTICE OF COMMERCIAL MARKETING PROVISION UNDERCUTS CONGRESS'S INTENT AND IMPOSES SIGNIFICANT UNINTENDED COSTS ON THE U.S. HEALTHCARE SYSTEM AND PATIENTS.

A. The Federal Circuit's interpretation would delay access to biosimilars by six months more than Congress intended, undercutting the BPCIA's careful balance between innovation and competition.

The Federal Circuit's holding that 180-day notice of commercial marketing of a biosimilar can only be effective after FDA licensure of the biosimilar effectively grants an RPS six additional months of exclusivity, beyond the 12-year exclusivity period expressly included in the BPCIA. 42 U.S.C. § 262(k)(7)(A). Under the BPCIA's express terms and FDA's reading of the statute, FDA cannot license a biosimilar until the RPS exclusivity expires. *Id.* (providing that FDA shall not "ma[k]e effective [its licensing of a biosimilar] until the date that is 12 years after the date on which the reference product was first licensed" by FDA). *See also* FDA, Draft Guidance, *Guidance for Industry: Reference Product Exclusivity for Biologics Products Filed Under Section 351(c) of the PHS Act* 2 (Aug. 2014) (describing 12-year exclusivity as "the period of time in which . . . FDA is not permitted to license a [biosimilars

application] that references a reference product.")[18] If the applicant cannot give notice until after FDA licensure, as the Federal Circuit held, the 180-day notice period will *always* add six months to the 12-year exclusivity, even where the reference product has no patent protection at all, or where patent disputes between the applicant and RPS have been resolved.

Granting the RPS an "extra-statutory exclusivity windfall" (Pet. App. 43a-44a (Chen, J., dissenting)) not only directly conflicts with the statute's plain text (Pet. Br. 30-39); it also thwarts the carefully-calibrated structure Congress created to increase competition in biologics markets while also preserving incentives to innovate. BPCIA § 7001(b), 124 Stat. at 804. Congress sought to balance these objectives by creating the biosimilars approval pathway while also, as a *quid pro quo* for brand biologics manufacturers, expressly granting an RPS 12 years – *not 12 years and six months* – of exclusivity, before the end of which no biosimilar version of the RPS's product could be approved. *See* Thomas M. Burton, *Biosimilar Drugs Face U.S. Test: FDA Panel Will Decide Whether to Recommend Approval*, Wall St. J., Jan. 6, 2015, at 2 ("The 2010 Affordable Care Act created an abbreviated pathway for biosimilars to enter the U.S. market . . . . As a tradeoff for the industry, the law gave biologic drugs a 12-year period of exclusivity that protected them from competition from a biosimilar.")[19]

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[18]http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm407844.pdf.

[19]http://www.wsj.com/articles/biosimilar-drugs-face-u-s-test-1420590926.

Because every day of exclusivity gives patients one less day of access to more affordable life-saving medicines, the length of the RPS exclusivity period was a particularly hard-fought piece of the overall innovation/competition compromise struck by Congress. The Federal Trade Commission argued that no exclusivity was needed to encourage innovation given patent protections and market pricing incentives, while the Obama Administration supported an exclusivity period of only seven years. Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 787-91 (Nov. 4, 2010); CRS Report at 3. In the end, the 12-year exclusivity was "vetted exhaustively" and was the product of "a genuinely bipartisan Member-level compromise" that was "reached in the summer of 2007 [and] remained intact through three subsequent years of legislative debate" until it "found its place in the final law." 65 Food & Drug L.J. at 816-17.

In these circumstances, Congress could not possibly have intended to extend the 12-year exclusivity through the indirect means of the notice provisions. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions – it does not, one might say, hide elephants in mouseholes.") (citations omitted). Indeed, when Congress chose to extend exclusivity beyond 12 years – *e.g.*, when the RPS conducts pediatric studies on the reference product – it did so explicitly. 42 U.S.C. § 262(m)(2)(A) (where pediatric studies are conducted, the 12-year

exclusivity "[is] deemed to be 12 years and 6 months rather than 12 years.")

By its very definition and as Congress intended (subject to specific, express modifications), the 12-year exclusivity period is intended to delay access to biosimilars for *no more than* 12 years. Yet the Federal Circuit's reading of the notice provisions would frustrate this basic congressional policy choice by making the end of the exclusivity period a secondary event and the end of the notice period, 180 days later, the primary triggering event for access to biosimilars. A reading of the BPCIA that allows notice to be given pre-FDA licensure, so that the notice period and exclusivity end at the same time and patients can enjoy access to a biosimilar immediately after 12 years, is the only reading that is consistent with "the whole [BPCIA] and . . . its object and policy." *United States Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (citation omitted). See also *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme.")[20]

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[20]The Federal Circuit compounded its error by incorrectly holding that this post-licensing notice requirement and the attendant six additional months of delayed access to biosimilars could be enforced through an automatic private injunction by the RPS. AHIP agrees with Sandoz (Pet. Br. 43-56) that Congress did not intend for the notice provision to be an enforceable right unto itself and that the Federal Circuit's reading, if upheld, would reinforce the unintended delays occasioned by its extra-statutory six-month extension of the RPS exclusivity period.

B. The Federal Circuit's interpretation of the notice provision, if upheld, would impose significant costs on our healthcare system and patients.

Allowing an RPS to delay access to biosimilars for an additional six months beyond Congress's chosen 12-year exclusivity period would result in significant costs to patients, businesses that offer health care coverage to their employees, private insurers, and taxpayers who fund public programs such as Medicare and Medicaid. These costs take several forms. For those who can afford expensive branded biologics, delayed availability of less expensive biosimilar versions of these products still means more dollars spent on medicines, contributing to increased prescription drug costs. But for those who *cannot* afford expensive branded biologics, these delays may mean no access at all to needed treatments, imposing further human and systemic costs.

The history of the drug product at issue in this case – filgrastim – exemplifies the overall problem. Filgrastim is used to reduce infections in certain cancer patients during chemotherapy. FDA first approved Amgen's branded filgrastim product, Neupogen®, in 1991, and for nearly a quarter-century Neupogen® faced limited competition in the marketplace, making Amgen $1.4 billion in 2015 alone. Express Scripts Infographic, *Two Biosimilars to Save $22.7 Billion* 2 (2016) ("*Express Scripts Infographic*").[21] On March 6, 2015, long after Amgen's

[21]http://lab.express-scripts.com/lab/insights/drug-options/infographic-two-biosimilars-to-save-227-billion#sthash.MexS3dpG.dpuf.

12-year BPCIA exclusivity and any patent protection had expired, FDA approved Sandoz's filgrastim biosimilar, Zarxio®. However, because of the Federal Circuit's ruling that Amgen could obtain an injunction requiring Sandoz to give 180-day notice of commercial marketing of Zarxio® after approval, Sandoz could not market Zarxio® until September 2015,[22] depriving patients of a lower-priced filgrastim product for six months after FDA had deemed Zarxio® ready for the market. One report estimates that this delay cost the U.S. healthcare system $270 million ($45 million per month). Express Scripts, *One Giant Leap for More Affordable Specialty Drugs* (Aug. 26, 2015).[23]

Similarly, Remicade®, Janssen's branded version of infliximab, which is used to treat inflammatory conditions like Crohn's disease, was first approved by FDA in 1998 and in 2015 earned $8.4 billion. *Express Scripts Infographic* 2. Even though a biosimilar infliximab product, Pfizer's Inflectra®, was approved by FDA on April 5, 2016, the Federal Circuit's ruling meant Pfizer could not market Inflectra® until after expiration of the 180-day notice period in fall 2016. When it did launch Inflectra®, Pfizer offered its product at a 15% discount from the price for

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[22]Novartis press release, *Sandoz launches Zarxio®TM (filgrastim-sndz), the first biosimilar in the United States* (Sept. 3, 2015), http://multimediacapsule.thomsonone.com/novartis/sandoz-launches-filgrastim-sndz.

[23]http://lab.express-scripts.com/lab/insights/drug-options/one-giant-leap-for-more-affordable-specialty-drugs.

Remicade®.[24] Express Scripts estimates that the availability of Inflectra® and Zarxio® together will save the U.S. healthcare system and patients $22.7 billion over the next decade. *Express Scripts Infographic* 2.

FDA has also approved within the past six months biosimilar versions of the anti-inflammatory drugs Humira® (adalimumab), the world's biggest-selling drug, and Enbrel® (etanercept). These products have enjoyed market monopolies for 15 and 20 years, respectively. But despite FDA's approvals, competition is being delayed at least in part by the Federal Circuit's decision.

To date, FDA has only approved four biosimilars, but it currently is considering 66 biosimilars programs for 20 different reference products. John Jenkins, M.D., Director, Office of New Drugs, Center for Drug Evaluation and Research, FDA, *Biosimilars in the U.S.: Progress and Promise* 7 (Oct. 27, 2016).[25] Moreover, one study has concluded that over 70 percent of the overall costs of biologics in 2013 was represented by drugs whose 12-year exclusivities have already expired, in some cases years ago. Milliman, Inc., *Understanding Biosimilars and Projecting the*

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[24]Pfizer press release, *Pfizer Announces The U.S. Availability Of Biosimilar INFLECTRA®® (infliximab-dyyb)* (Oct. 17, 2016), http://www.pfizer.com/news/press-release/press-release-detail/pfizer_announces_the_u_s_availability_of_biosimilar_Inflectra®_infliximab_dyyb.

[25]http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM526935.pdf.

Cost Savings to Employers 8 (June 29, 2015).[26] Congress cannot possibly have intended that all these products could enjoy six months of additional, post-12-year-exclusivity windfall profits, at the cost of billions of dollars to the U.S. healthcare system and patients.

II. THE FEDERAL CIRCUIT'S READING OF THE BPCIA'S APPLICATION-SHARING PROVISION ADVANCES THE STATUTE'S GOAL OF EXPEDITING PATIENTS' ACCESS TO AFFORDABLE MEDICINES.

While the Federal Circuit incorrectly interpreted the BPCIA's notice provision, it correctly read the provision governing a biosimilar applicant's sharing of its application with the RPS (42 U.S.C. § 262(l)(2)(A)) to give the applicant the option of not sharing this information and forgoing the patent dance.

A. The BPCIA allows biosimilar applicants to decide whether to provide their applications under subsection (l)(2)(A) and whether thereby to initiate the patent dance.

The BPCIA provides a flexible framework with several alternative approaches by which applicants and RPS's may address patent disputes. This framework does not envision that an applicant will be forced to provide its application – which may include confidential development and manufacturing information and/or trade secrets – to the RPS. Quite the contrary. Congress expressly envisioned that an

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[26] http://us.milliman.com/insight/2015/Understanding-biosimilars-and-projecting-the-cost-savings-to-employers-Update/.

applicant might *not* share this information and clearly set forth the consequences of this choice. If the applicant does not provide its application to the RPS, the statute expressly states the RPS may immediately bring an action for a "declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." 42 U.S.C. § 262(l)(9)(C). The BPCIA's amendments to the Patent Act confirm that Congress envisioned that an applicant might not share its application, providing that such a choice creates an act of infringement. 35 U.S.C. § 271(e)(2)(C)(ii).

Because Congress specified procedural, patent-litigation based consequences in the event an applicant did not share its application with the RPS, the Federal Circuit correctly declined to infer additional remedies, such as an automatic private injunction requiring the applicant to provide the application. *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001)) ("[P]rivate rights of action to enforce federal law must be created by Congress.").

B. Requiring all applicants to participate in the patent dance would frustrate the BPCIA's overall purpose and produce absurd results.

Congress included a range of patent dispute resolution options in the BPCIA for a reason – this layered framework was the approach most suited to advancing the overall objective of the BPCIA of expediting access to affordable medicines.

The goal of the patent provisions overall is to expedite disputes over patents that might be claimed to block the biosimilar. Congress enacted the patent dance process because it anticipated that *in certain cases*, adherence to that process would serve these ends. For example, where there is genuine uncertainty about the strength of patent protections asserted by the RPS, an extensive exchange of patent-related information might clarify the parties' positions and help determine the earliest possible date on which a biosimilar can become available.

But Congress clearly recognized there are other cases in which following these procedures might in fact *delay* resolution of the patent dispute, and where immediate litigation of this dispute, as provided for in 42 U.S.C. § 262(l)(9)(C), would best serve the BPCIA's overall goals. This is one such case. Here, Sandoz believed that Amgen had no valid patents that could block Sandoz's biosimilar version of Neupogen® and therefore concluded that the goal of access to Sandoz's Zarxio® biosimilar would best be served by immediate patent litigation, not by the information exchange contemplated in 42 U.S.C. § 262(l). Congress gave Sandoz in this case and biosimilar applicants generally the right to make that judgment. As the district court in this case explained:

> Sandoz's decision not to comply with subsection (l) reflects how the statute's overall scheme operates to promote expedient resolution of patent disputes. Compliance with the disclosure process affords [a biosimilars] applicant many benefits:

it allows the applicant to preview which patents the reference product sponsor believes are valid and infringed, assess related factual and legal support, and exercise some control over which patents are litigated and when. An applicant with a high (or unknown) risk of liability for infringement could benefit considerably from this process: it would be able to undergo the information exchange while protected by the statute's safe harbor from litigation, and if necessary, delay its product launch to protect the investment it made in developing its biosimilar.

On the other hand, subsection (l) lays out a process that could take up to 230 days – just to commence patent litigation. An applicant who values expedience over risk mitigation may believe that the disclosure and negotiation process would introduce needless communications and delay. Such an applicant may have good reason to believe that no unexpired relevant patents relate to its biosimilar, and that it is likely to prevail if challenged in an infringement suit. The applicant may, in such an instance, opt to forego its ability to bring certain types of declaratory actions and receive

> information about potentially relevant patents from the reference product sponsor, and instead commence litigation immediately.

Pet. App. 71a-72a.

Requiring that the applicant adhere to the information exchange procedures, even where doing so would delay resolution of patent disputes, would turn those procedures into ends unto themselves, rather than what Congress intended them to be – a means of advancing the BPCIA's overarching purposes. Moreover, this reading of the statute would produce the absurd results that an applicant would be required to share its application, containing confidential information and/or trade secrets, and engage in a time-consuming dispute resolution process *even where there are no disputes to be resolved*, for example where: (1) relevant patents are expected to expire before FDA completes its review of the application; (2) relevant patents will expire before the expiration of the 12-year statutory exclusivity period; or, most absurdly, (3) there are no relevant, unexpired patents even when the application is submitted. Congress carefully designed the BPCIA to avoid these nonsensical results, which directly undercut the statute's overarching purposes. *Griffin v. Oceanic Contractors*, 458 U.S. 564, 586 n.16 (1982) ("[T]o construe statutes so as to avoid results glaringly absurd . . . has long been a judicial function.").

CONCLUSION

For the foregoing reasons, the Federal Circuit's holding regarding the BPCIA's notice provision should be reversed, and its holding regarding the statute's information sharing provision should be affirmed.

Respectfully submitted.

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February 17, 2017

RECORD AND BRIEFS

FILED
FEB 17 2017
OFFICE OF THE CLERK
SUPREME COURT, U.S.

Nos. 15-1039 & 15-1195

IN THE
Supreme Court of the United States

SANDOZ INC.,
Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
Respondents.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
Cross-Petitioners,

v.

SANDOZ INC.,
Cross-Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF APOTEX INC. AND APOTEX CORP. AS *AMICI CURIAE* SUPPORTING SANDOZ INC.

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INTEREST OF *AMICI CURIAE*[1]

Amici Apotex Inc. and Apotex Corp. are subsidiaries of the global pharmaceutical company collectively known as Apotex,[2] which is one of the world's foremost generic drug and specialty pharmaceutical research and technology leaders.

Apotex is actively working to develop and manufacture a broad portfolio of biologic drug products. Apotex believes that the benefits of biosimilars will be significant for patients, payors, and providers, and it is dedicated to increasing public availability of more affordable versions of these life-saving therapies and to generating substantial savings for the American health care system.

Apotex agrees with Sandoz Inc. ("Sandoz") that reversal of the Federal Circuit is necessary to correct the interpretation of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). This decision, by a divided panel, has the effect of extending the monopolies for biologic products beyond the period specified by Congress, thereby delaying competition and consumer access to less-expensive medicines.

In recent years, Apotex has filed with the Food and Drug Administration ("FDA") applications under the BPCIA for pegfilgrastim and filgrastim, which are

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[1] Pursuant to Rule 37.6, counsel for *amici* certify that no counsel for a party authored this brief in whole or in part and that no person other than *amici* and their counsel made a monetary contribution intended to fund the preparation or submission of this brief. Counsel further certify that all parties have consented to the filing of this brief, and those written consents are being submitted contemporaneously with this brief.

[2] Apotex Inc. is an Ontario corporation and Apotex Corp. is a Delaware corporation. Both are wholly owned by Apotex Holdings, Inc.

biosimilar versions of the products Neulasta® and Neupogen®, respectively, marketed by Amgen Inc. and Amgen Manufacturing Ltd. (collectively, "Amgen"). Amgen subsequently sued Apotex in the United States District Court for the Southern District of Florida for patent infringement by Apotex's proposed pegfilgrastim biosimilar product.

In that case, the district court granted a preliminary injunction prohibiting Apotex from commercially marketing its biosimilar product until 180 days after first receiving its FDA license and then providing a notice of commercial marketing under the BPCIA.

Upon review of Amgen's case against Apotex, the Federal Circuit applied the construction of the BPCIA's notice of commercial marketing that is now before the Court, and affirmed the district court's grant of a preliminary injunction. *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1060-61 (Fed. Cir.), *cert. denied*, 137 S. Ct. 591 (2016). Apotex thus has a significant interest in the proper interpretation and application of the BPCIA.

INTRODUCTION

A. Statutory Background

This case arises from the Federal Circuit's erroneous construction and misapplication of the BPCIA, a part of the Patient Protection and Affordable Care Act of 2010. This comprehensive legislation was intended to strike a balance between encouraging competition among an important and rapidly growing category of costly specialty pharmaceuticals and incentivizing the development of new drugs.

The decision below amounts to a thumb on the scale for biologic manufacturers. The anticompetitive effects of prolonging the collection of monopoly rents by those manufacturers and bolstering already-troublesome barriers to entry for biosimilars, which are an important new class of medical products, will cost consumers and taxpayers hundreds of billions of dollars.

Prices for "biologics" – *i.e.*, large-molecule drugs that are produced in living organisms – are on average 22 times higher than prices for traditional chemical or small-molecule medications; biologics can cost more than $200,000 per year. *See* Comment of the Staff of the Federal Trade Comm'n to FDA at 3 (Oct. 27, 2015) (hereinafter "FTC Comment").[3] Moreover, prices are increasing by approximately 10-15% each year, with the average price of biologics having doubled from 2006 to 2012. *See id.* Nonetheless, in 2010, four of the 10 top-selling branded drugs worldwide were biologics, and industry experts

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[3] *Available at* https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-submitted-food-drug-administration-response-fdas-request-comments-its-guidance/151028fdabiosimilar.pdf.

estimated biologics would rise to seven of the top 10 in 2016. *See* Steve Miller, Express Scripts, Presentation at FTC Biosimilars Workshop: *Customer Perspective on Biosimilars* 3 (Feb. 4, 2014) ("Miller, *Customer Perspective on Biosimilars*").[4]

As part of an effort to promote competition and restrain these spiraling drug costs, Congress in the BPCIA established an abbreviated pathway for regulatory approval of follow-on biologics that are "highly similar" to the branded drug, which is referred to as the "reference product." 42 U.S.C. § 262(i)(2). The BPCIA recognizes the importance of encouraging innovation through a period of market exclusivity for the reference product. To that end, the FDA cannot finally approve an abbreviated Biologics License Application ("aBLA") for a biosimilar product until 12 years after the date on which the reference product was licensed, thus ensuring that the branded drug company, in this context referred to as the "reference product sponsor," enjoys 12 years of market exclusivity (and monopoly profits), regardless of whether it has any patent protection for its product. *See id.* §§ 262(k)(7)(A), 262(*l*)(1)(A). At the same time, however, the BPCIA encourages price competition once the sponsor's monopoly protection ends. The BPCIA therefore allows a biosimilar applicant to submit an aBLA and rely in part on the sponsor's FDA-approved license of a reference product. *See id.* § 262(k).

The BPCIA also established a detailed, carefully calibrated framework for the efficient resolution of

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[4] *Available at* https://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/miller.pdf.

patent disputes between the reference product sponsor and the biosimilar applicant. *See id.* § 262(*l*). Congress designed a series of choices in two stages, through which the biosimilar applicant may elect to share critical information with the reference product sponsor in an effort to streamline patent disputes. And at each such opportunity, the statute also offers the reference product sponsor recourse in the event the biosimilar applicant chooses not to share such information.

Stage 1: Information Exchange and Initial Litigation

In the *first* stage, under paragraphs (*l*)(2)-(*l*)(7) of the BPCIA,[5] the parties may exchange information concerning the aBLA, a list of patents for which a claim of patent infringement may be asserted against the biosimilar applicant, and statements concerning the patent(s), followed by negotiation to decide which patents should be the subject of an immediate patent-infringement action. Specifically, paragraph (*l*)(2)(A) provides that the biosimilar applicant "shall provide to the reference product sponsor a copy of the application submitted . . . under subsection (k), and such information that describes the process or processes used to manufacture the biological product that is the subject of such application," not later than 20 days after the FDA accepts the application for review. When the biosimilar applicant provides those paragraph (*l*)(2)(A) disclosures, its action initiates a series of exchanges under paragraphs (*l*)(3)-(*l*)(7), with each successive exchange reliant on the performance of one of more preceding exchanges.

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[5] The various provisions of 42 U.S.C. § 262(*l*) that are the subject of this brief may be referred to as "paragraph (*l*)__" throughout.

The result of this first-stage activity is a patent-infringement lawsuit and an updated list of potentially relevant patents that have not been included in the lawsuit.

But if the biosimilar applicant elects not to share its application and manufacturing information with the reference product sponsor under paragraph (*l*)(2)(A), then paragraph (*l*)(9)(C) provides the reference product sponsor with a remedy: "If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or use of the biological product."

Stage 2: Enforcement and Dispute Resolution

In the *second* stage for resolving patent disputes, under paragraph (*l*)(8)(A), the biosimilar applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." When the applicant gives notice, the sponsor may seek an injunction under paragraph (*l*)(8)(B): "After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent" that was described as relevant during the information

exchange outlined in paragraph (*l*)(3) and that is not already the subject of litigation.

If the biosimilar applicant elects not to give notice of commercial marketing under paragraph (*l*)(8)(A), then paragraph (*l*)(9)(B) also provides the reference product sponsor with a remedy: "If a subsection (k) applicant fails to complete an action required of the . . . applicant under . . . paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, for a declaration of infringement, validity, or enforceability of any patent" submitted to be relevant during the information exchange described in paragraphs (*l*)(2)-(*l*)(5), including any newly issued patent deemed relevant.

B. Procedural Background

The decision under review became the Federal Circuit's first case interpreting the BPCIA. In this case, Sandoz elected not to provide the information specified in paragraph (*l*)(2)(A). And the Federal Circuit held that Sandoz was not required to do so, confirming that the information exchange described in paragraphs (*l*)(2)-(*l*)(5) is optional and that paragraph (*l*)(9)(C) provides an appropriate remedy to the reference product sponsor in the event that a biosimilar applicant elects not to engage in the information exchange. Pet. App. 18a.[6] The Federal Circuit also held that a biosimilar applicant such as Sandoz that chooses not to engage in the information exchange described in paragraph (*l*)(2)(A) must provide to the reference product sponsor the notice of commercial marketing described in paragraph (*l*)(8)(A). *See id.*

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[6] References to "Pet. App. __a" are to the appendix to the certiorari petition filed in No. 15-1039.

at 26a ("We therefore conclude that, where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the [reference product sponsor] by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory."). The court further held that such an applicant could provide that notice of commercial marketing only after the issuance of the FDA license for its biosimilar product. *Id.* at 21a-22a.

But the Federal Circuit left unanswered how its limited rulings regarding the paragraph (*l*)(8)(A) notice of commercial marketing should be applied to scenarios in which a biosimilar applicant did chose to participate in the paragraph (*l*)(2)(A) information exchange. The court of appeals answered that critical question in a companion case, *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir.), *cert. denied*, 137 S. Ct. 591 (2016).

A brief summary of the facts of the *Apotex* case follows. In 2002, Amgen received a license for a brand-name biologic with the active ingredient pegfilgrastim. *Id.* at 1055. In 2014, Apotex applied for an FDA license to market a biosimilar pegfilgrastim product in accordance with the BPCIA. *Id.* After the FDA accepted Apotex's application for review, Apotex timely provided Amgen with a copy of that application and the other information specified in paragraph (*l*)(2)(A). *Id.* at 1059. Thereafter, Apotex and Amgen engaged in the exchange of patent information contemplated by paragraphs (*l*)(3)-(*l*)(5). Apotex also attempted to provide Amgen with the notice of commercial marketing described in paragraph (*l*)(8)(A). *Id.* The parties ultimately agreed to litigate all unexpired patents, of which there is currently only one remaining. *Id.*

Amgen subsequently filed its complaint in the United States District Court for the Southern District of Florida. The district court granted a preliminary injunction prohibiting Apotex from commercially marketing its biosimilar product until waiting 180 days after first receiving its FDA license and then providing a new notice of commercial marketing. *Id.* at 1060.

On appeal, the Federal Circuit discounted the significant factual distinctions between the *Apotex* case and *Sandoz* – namely, that Apotex faithfully engaged in the information exchange precipitated by the paragraph (*l*)(2)(A) disclosures and that all relevant patents had thereby already become the subject of litigation. Relying on the *Sandoz* decision now under review, the Federal Circuit decreed, *first*, that applicants are required to provide a notice of commercial marketing "whether or not a (2)(A) notice was given" and, *second*, that "[t]he (8)(A) requirement of 180 days' post-licensure notice . . . [is] enforceable by injunction." *Id.* at 1060-61.

Regarding the former holding, the Federal Circuit reasoned that "[t]he language of (8)(A) is categorical" because "[i]t contains no words that make the applicability of its notice rule turn on whether the applicant took the earlier step of giving the (2)(A) notice that begins the § 262(*l*) information-exchange process" and because "[t]here . . . is no other statutory language that effectively compels a treatment of (8)(A) as non-mandatory." *Id.* at 1061. The court of appeals also rejected the argument "that paragraph (9) of § 262(*l*) makes a declaratory-judgment action, discussed in (9)(B), the exclusive remedy for violations of (8)(A)." *Id.* at 1063.

Regarding the timing of the notice of commercial marketing and the injunctive relief granted to Amgen, the Federal Circuit reasoned that the BPCIA "establishes the 12-year date only as an earliest date, not a latest date, on which a biosimilar license can take effect" and that, in any case, "any . . . delay beyond 12 years should occur less and less as time goes by" because, "as time passes, more and more of the reference products will be newer, and a biosimilar-product applicant, entitled to file an application a mere four years after licensure of the reference product, . . . can seek approval long before the 12-year exclusivity period is up." *Id.* at 1061-62 (citing Pet. App. 22a).

Taken together, the Federal Circuit's decisions in *Sandoz* and *Apotex* rob biosimilar applicants such as Apotex and Sandoz of a central tenet of the BPCIA's design, *viz.*, control over the scope of the first-stage patent litigation by the applicant under paragraph (*l*)(2)(A). The court of appeals' holdings award reference product sponsors such as Amgen a new, extra-statutory remedy: an injunction against commercial marketing of an FDA-approved biosimilar product until 180 days after post-approval notice is given. This exclusivity windfall exceeds the 12-year exclusivity period granted by Congress.

SUMMARY OF ARGUMENT

Congress struck a careful balance in the BPCIA between, on the one hand, encouraging competition to lower the soaring prices for biologic medications and, on the other hand, maintaining incentives for the development of new drugs. It did so by coupling an abbreviated pathway to expedite the market availability of biosimilar products with a 12-year period of exclusivity for branded reference products.

I. The Federal Circuit erroneously held that 42 U.S.C. § 262(*l*)(8)(A) requires that a biosimilar applicant wait until after it receives FDA approval before providing effective notice of commercial marketing to the reference product sponsor. The court also erred in creating an extra-statutory injunctive remedy for reference product sponsors in the event biosimilar applicants choose not to provide such notice. Those decisions have the effect of extending the 12-year exclusivity period and delaying the onset of price-lowering competition from biosimilar products. The Federal Circuit's erroneous interpretation of this important new framework is contrary to the statute's plain text and purpose.

Paragraph (*l*)(8)(A) provides that a "subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." Although the use of the word "shall" in isolation implies a mandatory obligation, the text of the statute as a whole indicates that is the case only for those biosimilar applicants that wish to avail themselves of the enumerated expedited procedures.

The Federal Circuit recognized as much, holding that, although the BPCIA repeatedly directs that a

biosimilar applicant "shall" take certain actions, it is not always the case that they "must" do so. Pet. App. 14a-15a. The Federal Circuit explained that "'shall' in paragraph (*l*)(2)(A) does not mean 'must'" because, among other provisions, paragraph (*l*)(9)(C) "explicitly contemplates that a subsection (k) applicant might fail to disclose the required information by the statutory deadline" and provides a consequence for the applicant's failure to do so. *Id.* at 15a-16a.

That same logic applies with full force to the BPCIA's notice of commercial marketing provision. Paragraph (*l*)(9)(B) provides the exclusive remedy to reference product sponsors in the event that an applicant elects not to provide the notice of commercial marketing described in paragraph (*l*)(8)(A): "*If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under . . . paragraph (8)(A)*, the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, for a declaration of infringement, validity, or enforceability" of those patents raised during the earlier information exchange between the parties. The Federal Circuit's imposition of an injunction to enforce its flawed interpretation of paragraph (*l*)(8)(A) as mandatory thus renders the paragraph (*l*)(9)(B) penalty provision superfluous.

Moreover, the court's ruling produces consequences that contravene the legislative intent of the BPCIA to facilitate the early resolution of patent disputes between the parties. For example, the BPCIA does not require a biosimilar applicant to give notice of commercial marketing if it made the disclosures set forth in paragraph (*l*)(2)(A) and fully engaged in the subsequent patent resolution framework. Under such

circumstances, a notice of commercial marketing serves no purpose. If paragraph (*l*)(8)(A) were mandatory for applicants who complied with paragraph (*l*)(2)(A) and engaged in the information exchange described in paragraphs (*l*)(3)-(*l*)(5), then reference product sponsors would have no need of the remedy specified in paragraph (*l*)(9)(B). Thus, with no further patent rights remaining for the reference product sponsor to assert, an approved biosimilar product is needlessly kept off the market for an additional 180 days.

II. The Federal Circuit's erroneous decision is inconsistent with Congress's purpose in decreasing the total health care costs of the United States government and the American people. If upheld, the Federal Circuit's statutory interpretation will delay patient access to more affordable biosimilar medicines.

New competition between branded reference products and biosimilars can help ameliorate rising health care costs and is expected to translate into major savings for consumers, including public-sector health plans and the federal government. Lower prices also mean better consumer access.

The Federal Circuit's decision will delay Americans' realization of those economic and medical benefits – thwarting Congress's years-long effort to close the biologics loophole in the Hatch-Waxman Act. The BPCIA completed a project three decades in the making: balancing cost competition and innovation for all types of pharmaceuticals. And its framework for the abbreviated approval of biosimilars is arguably even more essential to health care today than when the Hatch-Waxman Act was enacted in 1984.

To ensure that Americans are able to realize the benefits of biosimilars and of continued brand-name

biologic innovation, Congress specifically prescribed a 12-year period of exclusivity for brand-name reference products.[7] By extending that exclusivity period in all cases, the Federal Circuit's decision impedes Americans' access to life-saving biosimilar drugs and could add billions of dollars to household and government health care costs.

ARGUMENT

The Federal Circuit's decision misreads the BPCIA's text and upsets Congress's careful balance between cost-saving competition and life-saving innovation. Congress sought to promote the former through the creation of an abbreviated pathway for the approval of biosimilar products and the latter by preserving a 12-year exclusivity period for brand-name reference product sponsors. The Federal Circuit threw up a roadblock in the abbreviated pathway by mandating that biosimilars provide a notice of commercial marketing even when doing so cannot advance the orderly resolution of patent disputes. And, adding insult to injury, the court's rulings functionally extended the 12-year exclusivity period by an extra six months, diverting hundreds of billions of dollars from taxpayers and health care consumers to biologic manufacturers. Together, those errors impermissibly favor reference product sponsors. If not corrected, they will substantially increase

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[7] In fact, the Obama Administration's Office of Management and Budget ("OMB") proposed reducing the market exclusivity period afforded to reference product sponsors from 12 years to 7 years in order to achieve $3 billion in savings over 10 years to federal health programs including Medicare and Medicaid. *See* OMB, Exec. Office of President, *Fiscal Year 2014: Budget of the U.S. Government* 40 (Apr. 2013), *available at* http://www.whitehouse.gov/sites/default/files/omb/budget/fy2014/assets/budget.pdf.

Americans' health care costs and needlessly delay access to life-saving biosimilar medications.

I. THE FEDERAL CIRCUIT MISREAD THE BPCIA

A. The BPCIA Allows Biosimilar Applicants To Give Notice Of Commercial Marketing Before FDA Approval

The Federal Circuit is incorrect that biosimilar applicants must wait to give effective notice of commercial marketing under 42 U.S.C. § 262(*l*)(8) only after the FDA has approved a biosimilar application substantially for the reasons that Judge Chen gave in his cogent dissent. The court also erred in creating an injunctive remedy in the event a biosimilar applicant chooses not to give notice of commercial marketing. The Federal Circuit's ruling is inconsistent with the statute's text and the purpose of the notice provision. And the ruling has the pernicious and costly effect of automatically granting the reference product sponsor a 180-day windfall of extra monopoly profits after FDA approval of a biosimilar application, all to the detriment of patients who need and deserve more affordable biosimilar options. If Congress had wanted to impose a 12-and-a-half-year waiting period before biosimilar products could be brought to market, it could have done so. Instead, Congress enacted a 12-year waiting period. The Federal Circuit should have respected that carefully considered legislative choice.

1. The BPCIA's Plain Text Neither Requires a Waiting Period Nor Provides an Injunctive Remedy for Lack of Notice

Paragraph (*l*)(8)(A) calls on a biosimilar applicant to "provide notice to the reference product sponsor

not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). The product to be marketed commercially will, of course, need to be licensed before it can be marketed, and the passage makes clear that notice is required for biosimilar applicants seeking approval under subsection (k) (as contrasted with the traditional pathway for biologics approval under subsection (a)).

On its face, however, this provision says nothing about FDA approval being required before notice is given. The notice requirement is imposed on the "subsection (k) applicant," a choice of words that strongly suggests that notice can be given before the application has been approved. If Congress had thought otherwise, it would have imposed the requirement on the "subsection (k) licensee," or otherwise have denoted the completion of the application process. The Federal Circuit nevertheless ruled that the phrase "licensed under subsection (k)" carried with it the requirement that the product be licensed not only before commercial marketing but also before effective notice of commercial marketing can be given. This reading places more interpretive weight on the word "licensed" than it can reasonably bear when the phrase is considered in the context of the statute as a whole.

Furthermore, the Federal Circuit's ruling that commercial marketing could be enjoined in this case until 180 days after FDA approval is in tension with paragraph (*l*)(9)(B) of the statute. That provision prescribes the remedy in the event that the biosimilar applicant elects not to provide notice of commercial marketing:

> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under . . . paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

42 U.S.C. § 262(*l*)(9)(B). The court correctly recognized that "paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with [the information-exchange provisions of] paragraph (*l*)(2)(A)." Pet. App. 25a. The court concluded, however, that the provision "does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." *Id.* The Federal Circuit then crafted its own extra-statutory remedy – an injunction preventing commercial marketing until 180 days after notice has been given – to fill in what it regarded as a gap in the statute.

There is no gap to fill, however. As Judge Chen explained in his dissent, "the absence of such a remedial provision in (*l*)(9)(B) *confirms* that Congress deemed any additional remedy to be unnecessary." *Id.* at 51a (Chen, J., dissenting-in-part). A reference product sponsor does not need the remedy in paragraph (*l*)(9)(B) if the biosimilar applicant does not comply with paragraph (*l*)(2) because, if that happens, other provisions of the law – 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii), to be precise – "already grant the right to file, immediately, an unrestricted patent infringement action." Pet. App. 51a (Chen, J., dissenting-in-part). The Federal

Circuit thus distorted the remedial scheme created by Congress to fill an imagined gap in the scheme that does not exist.

2. Imposing a Waiting Period Is at Odds with the Purpose of the BPCIA Patent Dispute Resolution Provisions

The purpose of the paragraph (*l*)(8)(A) notice is to allow the reference product sponsor to seek relief under paragraph (*l*)(8)(B), which provides:

> After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—
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> (i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and
>
> (ii) not included, as applicable, on—
>
> (I) the list of patents described in paragraph (4); or
>
> (II) the lists of patents described in paragraph (5)(B).

42 U.S.C. § 262(*l*)(8)(B). That is, the reference product sponsor may seek to prevent the biosimilar applicant from launching its biosimilar product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that was listed as relevant under paragraph (*l*)(3)

but not included in the lists of patents for early litigation that were agreed upon under paragraph (*l*)(4) or selected for litigation by the procedure of paragraph (*l*)(5). Paragraph (*l*)(8)(B) thus addresses patents that are *not* already the subject of a lawsuit between the parties. The provision is necessary because without it paragraph (*l*)(9)(A) would prevent the reference product sponsor from asserting the patents on the paragraph (*l*)(3) list that were not already in litigation.

Very often, there will be no such patents. For example, in Amgen's own subsequent litigation with Apotex concerning a biosimilar version of pegfilgrastim, all of the patents identified as relevant under paragraph (*l*)(3) were already part of the lawsuit. Amgen had no additional patents to add to the case after receiving notice of commercial marketing. Under those circumstances, if notice of commercial marketing is required at all, then requiring Apotex to wait to give notice of commercial marketing until after the FDA has approved its biosimilar application under subsection (k) serves no purpose; the delay in giving notice extends by 180 days the period of time in which patients and insurers must pay monopoly prices to the seller of the branded reference product even though the seller cannot use that time to resolve additional patent disputes.

Indeed, Amgen tried and lost its patent case against Apotex. The district court concluded that Apotex's manufacturing process did not infringe Amgen's patent. *See* Findings of Fact and Conclusions of Law at 19-26, *Amgen Inc. v. Apotex Inc.*, No. 15-61631-CIV-COHN/SELTZER (S.D. Fla. Sept. 6, 2016) (reproduced in the appendix to Apotex's certiorari petition filed in No. 16-332 at 59a-67a);

Final Judgment at 1, *Amgen Inc. v. Apotex Inc.*, No. 15-61631-CIV-COHN/SELTZER (S.D. Fla. Sept. 6, 2016) (reproduced in the appendix to Apotex's certiorari petition filed in No. 16-332 at 71a). Thus, Amgen exhausted its patent rights, and the "categorical" 180-day injunction imposed by the Federal Circuit in Amgen's case against Apotex will operate only to keep a non-infringing, cost-saving, FDA-approved biosimilar product out of the hands of consumers for six months longer than Congress intended. *See Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1062 (Fed. Cir.), *cert. denied*, 137 S. Ct. 591 (2016).

Even when there are additional relevant patents to assert, moreover, the purpose of the notice provision is more logically fulfilled *before* the FDA approval of the subsection (k) application than afterward. The BPCIA created an artificial act of infringement based on the filing of the application under subsection (k), which allows the reference product sponsor to assert its patents against the biosimilar applicant before the application has been approved. If, however, notice of commercial marketing could be given only after FDA approval, then there would be no need for the artificial act of infringement that the BPCIA creates. Instead, the patent owner could bring a conventional declaratory judgment suit and seek a preliminary injunction without the need for the early patent dispute resolution procedures that the BPCIA makes available.

B. The Federal Circuit's Ruling Is Inconsistent With Other BPCIA Provisions

Congress plainly expected that biosimilar applicants and reference product sponsors would engage in the information exchange and patent negotiations

described in paragraphs (*l*)(2)-(*l*)(5) and (*l*)(7).[8] The Court should therefore evaluate the meaning of the

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[8] *See Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on Judiciary*, 111th Cong. 9 (2009) (hereinafter "*Biologics and Biosimilars*") (statement of Rep. Eshoo) ("H.R. 1548 also establishes a simple, streamlined patent resolution process. This process would take place within a short window of time, roughly 6 to 8 months after the biosimilar application has been filed with the FDA. It will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large. . . . Once a biosimilar application is accepted by the FDA, the agency will publish a notice identifying the reference product and a designated agent for the biosimilar applicant. After an exchange of information to identify the relevant patents at issue, the applicant can decide to challenge any patents' validity or applicability."), *available at* https://judiciary.house.gov/_files/hearings/printers/111th/111-73_51014.PDF; *id.* at 197 (statement of Teresa S. Rea, President, American Intellectual Property Law Association) ("[H.R. 1548] addresses the need for an exchange of information concerning the follow-on product to allow a preliminary infringement analysis. The notice and certification provisions in H.R. 1548 would limit the patents that may be challenged to those which the patent holder believes are infringed by the follow-on product."); *see also* Krista H. Carver *et al.*, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 802-06 (2010) (describing how the patent provisions of H.R. 1548 were incorporated into the final legislation), *available at* https://www.cov.com/-/media/files/corporate/publications/2010/01/an-unofficial-legislative-history-of-the-biologics-price-competition-and-innovation-act-of-2009.pdf; *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 116 (2007) (hereinafter "*Assessing the Impact*") (statement of Bruce Downey, Chairman of the Board, Generic Pharmaceutical Association) ("I think we need to have a provision that would permit resolution of intellectual property disputes

paragraph (*l*)(8)(A) notice provision against the other BPCIA provisions that inform Congress's intent.

The Federal Circuit's ruling that effective notice of commercial marketing can be given only after FDA approval of the biosimilar product means that, whenever notice is required before commercial marketing can begin, the 12-year statutory exclusivity period will be extended by 180 days. The court appears not to have fully appreciated this consequence of its decision. The court stated that "requiring FDA licensure before notice of commercial marketing does not necessarily conflict with the twelve-year exclusivity period of § 262(k)(7)(A)." Pet. App. 22a. In support of this conclusion, the court reasoned that, although the rule resulted in an extra 180 days of exclusivity in the present case (in which the biosimilar application had been filed only after the expiration of the 12-year exclusivity period), "[t]hat extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." *Id.* This statement is a *non sequitur*. It makes no difference whether the application is filed within the 12-year exclusivity period or afterwards. If the FDA cannot approve a biosimilar application before the expiration of the 12-year exclusivity period, and if effective notice of commercial marketing cannot be given before FDA

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in advance of launching the product. . . . Many of these products do not have one or two patents, but 30, 40 patents and there are disagreements about whether we infringe or if they are valid, and there needs to be a mechanism that allows those issues to be decided before there is a launch of the product that allows both innovator and generic companies to manage the risks that they confront . . . ."), *available at* https://archive.org/details/gov.gpo.fdsys.CHRG-110hhrg40500.

approval of the biosimilar application, then, in any case in which notice is required, the applicant will need to wait an extra 180 days after the 12-year exclusivity period has expired before commercial marketing can begin. The court thus erred in creating this "extra-statutory exclusivity windfall." *Id.* at 44a (Chen, J., dissenting-in-part).

Moreover, the BPCIA does not require a biosimilar applicant to give notice of commercial marketing if it made the disclosures set forth in paragraph (*l*)(2)(A) and fully engaged in the subsequent first-stage patent resolution framework. Under such circumstances, a notice of commercial marketing serves no purpose.

Amgen's case against Apotex illustrates the severe consequences of the Federal Circuit's erroneous interpretation. Unlike Sandoz here, biosimilar applicant Apotex in that case chose to comply with the information exchange provisions of paragraphs (*l*)(2)-(*l*)(5). Thus, Apotex provided reference product sponsor Amgen with all of the information needed to litigate the relevant patents, which concluded with a judgment of non-infringement. *See supra* pp. 8-9, 19-20. Thus, in that case, Amgen has no more patent rights to assert when the FDA grants authorization for Apotex to commence commercial marketing its biosimilar product, but the bar imposed by the Federal Circuit means the American people will nevertheless have to wait an additional 180-days after FDA approval for Apotex's pegfilgrastim product to enter the market.[9]

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[9] The Federal Circuit has suggested that "the FDA may . . . issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date." *Apotex*, 827 F.3d at 1062. But such speculation finds no basis in fact: there is currently no FDA policy for licensing applications prior to the expiration of

II. THE FEDERAL CIRCUIT'S DECISION CANNOT BE RECONCILED WITH THE BPCIA'S LEGISLATIVE HISTORY AND PURPOSES

The Federal Circuit read the BPCIA as having the purpose of preserving the market share of reference product sponsors. In fact, the statute was intended to increase the availability of biosimilar products by balancing the interests of reference product sponsors and biosimilar applicants and, more broadly, to balance the national interests in innovation and cost competition. Requiring a notice of commercial marketing in all cases and extending the 12-year exclusivity window upends Congress's intended balance.

A. The BPCIA Is Designed To Increase Price Competition From Biosimilar Market Entry

In a recent submission to the FDA, the FTC recognized that "[b]iosimilar competition is important because biologics are among the most promising medicines for the treatment of a variety of medical conditions for which patients have no other alternative." FTC Comment at 2-3. The FTC further noted that "the relatively high prices of biologics, combined with patient cost-sharing requirements, can limit patient access to biologics. Price competition from biosimilars would likely lead to reduced prices for, and thus greater patient access to, biologics and biosimilars." *Id.* at 3 (footnote omitted).

The FTC has predicted that, with expected discounts of up to 30% of the brand biologic product

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the exclusivity period. *See* FDA, *Memorandum re: Exclusivity Expiry for Neupogen (filgrastim) BLA 103353* (June 26, 2014), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125553Orig1s000AdminCorres.pdf.

price, consumers stand to benefit significantly from the new market competition between lower-cost but similarly effective biosimilars. *Id.* at 5. Industry estimates suggest this competition could save consumers, including the federal government, as much as $250 billion by 2024. *See* Miller, *Customer Perspective on Biosimilars* at 7.

Congress recognized the benefits of cheaper, more widely available generic drugs in the markets for traditional small-molecule chemical medicines three decades ago. With the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, known more commonly as the Hatch-Waxman Act, Congress crafted a framework with what this Court has called a "procompetitive thrust" designed both to preserve incentives for brand-named innovation and to speed the introduction of low-cost generic drugs to market. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2234 (2013); *see Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). The resulting surge of cheaper generic products produced significant savings for consumers. According to the Government Accountability Office ("GAO"), the total savings that accrued to the U.S. health care system from substituting small-molecule generic chemical drugs for their brand-name counterparts from 1999 to 2010 amounted to more than $1 trillion. *See* Letter from John E. Dicken, Health Care Dir., GAO, to Hon. Orrin G. Hatch, Ranking Member, Senate Comm. on Finance, at 4, 10 (Jan. 31, 2012).[10]

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[10] *Available at* http://www.gao.gov/assets/590/588064.pdf.

But the abbreviated approval pathway under the Hatch-Waxman Act applied only to *bioequivalent* drugs (*i.e.*, chemical, small-molecule drugs) regulated under the Federal Food, Drug, and Cosmetic Act. In contrast, *biosimilar* drugs (*i.e.*, biologic, large-molecule drugs) regulated under the Public Health Service Act still required full, individual FDA testing and approval. That asymmetry rendered biologics broadly immune to the downward pricing pressures that affected traditional drugs. *See* Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 Health Matrix 139, 144-46 (2015).[11] Thus, the BPCIA was intended to update the American drug-approval system in keeping with global trends toward increased use of biosimilars.

Although the BPCIA is distinct from the Hatch-Waxman Act and there are significant differences between the two statutes, both share the same basic theoretical framework and use similar procedures to attain similar goals. Notably, both statutes aim to improve access to high-cost medications for populations in need while preserving the incentives to innovate new treatments and facilitating the timely identification and resolution of patent disputes. But the Federal Circuit's decision, which essentially affords reference product sponsors an automatic 180-day injunction barring sales of biosimilar drugs whenever notice of commercial marketing is required, frustrates the purpose of the statute and endangers the calculated tradeoff between price-lowering competition and incentive for innovation. Biosimilars already face significant barriers to market entry that are much more difficult to overcome than those

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[11] *Available at* http://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1021&context=healthmatrix.

typically confronting small-molecule generic chemical drugs. These barriers include difficulties associated with manufacturing, marketing, storage, distribution, delivery devices, immunogenicity (*i.e.*, adverse reactions in a patient due to live organisms), and special requirements for pharmacovigilance (*i.e.*, post-sale monitoring). *See* Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 Am. Health & Drug Benefits 469, 471 (Sept./Oct. 2013).[12] An unnecessarily lengthy, unintended, and unwarranted extension of the exclusivity period will impede access to biosimilars and add hundreds of billions of dollars in costs to consumers, employers, and publicly funded programs like Medicare and Medicaid.

B. Congress Determined That A 12-Year Exclusivity Period Struck The Right Balance Between The Competing Interests

The 12-year window was a carefully negotiated compromise – a "middle ground between innovator and generic interests." Carver, *An Unofficial Legislative History*, 65 Food & Drug L.J. at 817. Defining an exclusivity period that would best promote both innovation and cost-saving generic competition was a key sticking point across years of legislative negotiations. *See id.* at 724-25 (noting that exclusivity proved early on to be a "troublesome" point of disagreement). In fact, even during final negotiations over the bill, proposals under consideration included exclusivity periods as long as 14 years and as short as five to seven. *See id.* An unnecessarily lengthy, unintended, and unwarranted extension of the exclusivity period will impede access to biosimilars and add

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[12] *Available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/pdf/ahdb-06-469.pdf.

hundreds of billions of dollars in costs to consumers, employers, and publicly funded programs like Medicare and Medicaid.

Members of Congress weighed the competing interests of sponsors and applicants and of innovation and cost competition. They emphasized the need to strike a "balance" that would "allow generic companies to do what they do best – bring low-cost versions to the market." Senate Comm. on Health, Education, Labor & Pensions, Press Release, *Lawmakers Praise Committee Passage of Biologics Legislation* (June 27, 2007) (statement of Sen. Hatch).[13] Their aim was "to lower prices and extend the availability of . . . treatments to more who need them." *Id.* (statement of Sen. Clinton). The congressional record is full of testimony from lawmakers of both parties and from others who repeatedly emphasized the importance of achieving cost savings to improve patient access.

For example, in a hearing before a Subcommittee of the House Committee on Energy and Commerce, Rep. Frank Pallone, Jr. called on Congress to "produce measurable savings." *Assessing the Impact* at 2. Representative Nathan Deal concurred, offering that Congress had before it "an opportunity to provide patients access to a lower cost alternative for their needed medications." *Id.* at 5. Likewise, the Vice President of Human Services at Caterpillar, Inc., told the Senate Committee on Health, Education, Labor, and Pensions that biologic drugs accounted for an outsized and increasingly unaffordable slice of the company's health care expenses, describing the rising costs as "simply not sustainable." *Follow-On Biologics:*

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[13] *Available at* http://www.help.senate.gov/ranking/newsroom/press/lawmakers-praise-committee-passage-of-biologics-legislation.

Hearing Before the S. Comm. on Health, Education, Labor, and Pensions, 110th Cong. 11 (2007).[14] In the same hearing, Sen. Charles Schumer acknowledged the national scope of the problem and put the potential for cost savings in perspective: "Treating [a] patient with a biologic drug can cost $100,000 a year, total cost to the nation, $32 billion. If introducing competition in this market lowers the price of biologics even by only 10 to 25 percent, the savings are astronomical." *Id.* at 6.[15]

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[14] *Available at* https://www.gpo.gov/fdsys/pkg/CHRG-110shrg34053/pdf/CHRG-110shrg34053.pdf.

[15] *See also Safe and Affordable Biotech Drugs: The Need for a Generic Pathway: Hearing Before the H. Comm. on Oversight and Gov't Reform*, 110th Cong. 2-3 (2007) (statement of Rep. Waxman) ("A new path for FDA to approve generic biologicals will save patients billions in the future and will improve access to treatments and cures . . . . For the sake of patients, their families, public and private health insurance, and taxpayers, we must find a way to introduce competition to this market. When a patent expires, we owe it to consumers to find a way through competition to lower prices and still deliver a safe and effective product."), *available at* https://www.gpo.gov/fdsys/pkg/CHRG-110hhrg40874/pdf/CHRG-110hhrg40874.pdf; *Assessing the Impact* at 7 (statement of Rep. Ferguson) (noting importance of both patient safety and cost savings and, in particular, pointing to expectation that "follow-on biologics will save about $3.6 billion over 10 years"); *id.* at 9 (statement of Rep. Blackburn) ("[w]hen the healthcare costs are skyrocketing, and we hear this every time we come in for a committee hearing, we know that people are looking for new options for lowering drug costs"); *id.* at 10 (statement of Rep. Capps) ("Quite frankly, with no competition on the markets, biologics remain out of economic reach for most of the people who need them. I hope to hear today from witnesses on how we can balance innovation with patients' needs for cheaper, more accessible drugs."); *id.* at 11 (statement of Rep. Solis) ("The manufacture of biologic medicines has the potential to save millions of lives, and biologics account for approximately $30 billion in sales. However, the cost of devel-

Ultimately, Congress provided for a 12-year exclusivity period that was intended to be commensurate in duration and scope to the patent protection typically afforded to innovative drugs.[16] And, like patent protections, the 12-year exclusivity period is not open-ended. Indeed, the congressional sponsor of key patent resolution provisions underscored the point: "In order to protect the rights of all parties and ensure that all patent disputes involving a biosimilar are resolved *before, and I emphasi[ze] the word before*, the expiration of the data-exclusivity period, H.R. 1548 also establishes a simple, streamlined patent resolution process." *Biologics and Biosimilars*

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oping and manufacturing these biologics are extremely high; and the average cost of a 1-day supply of biologic medicines is $45. As a result, the cost for patients, insurers, private companies, and Government payers are quickly growing. And I am very concerned about the high cost of these medicines, especially the cost of those treatments for many who lack healthcare insurance or who are underinsured."); *id.* at 12 (statement of Rep. Wilson) ("I commend the chairman and members of his committee for their determination to tackle this issue to see whether there is something we can do so that we create a pathway for generics that might be at less cost for a new class and a new kind of therapy in the area of medicine.").

[16] *See Biologics and Biosimilars* at 8 (statement of Rep. Eshoo) ("[T]o preserve the existing incentives for investment and innovation, the Pathway for Biosimilars Act provides a data-exclusivity period equivalent to patent protections for small molecules. The Congressional Budget Office has determined that 11.5 years is the average length of time that drugs are marketed under patent. In other words, innovative drugs and biologics typically stay on the market for about 12 years before facing competition. My legislation maintains this level of protection for biologics.").

at 9 (statement of Rep. Eshoo) (emphasis added);[17] *see also Assessing the Impact* at 116 (statement of Bruce Downey, Chairman of the Board, Generic Pharmaceutical Association) ("[T]here needs to be a mechanism that allows [patent] issues to be decided before there is a launch of the product that allows both innovator and generic companies to manage the risks that they confront and . . . *also allows for the earliest lawful entry of the product and doesn't allow the litigation post-exclusivity period, post-patent to delay the launch of a product.*") (emphasis added). Any assertion to the contrary undermines Congress's explicit effort to make cost-saving biosimilars available at the earliest possible date consistent with continuing innovation.

C. Notice Of Commercial Marketing Is Not Necessary In All Cases

Requiring a notice of commercial marketing in all cases cannot be justified by reference to Congress's intent to promote the introduction of biosimilar products, including by facilitating the resolution of patent disputes arising between sponsors and biosimilar applicants.

The Federal Circuit's decision erroneously requires *all* biosimilar applicants to wait an additional 180 days before undertaking to commercially market an aBLA product, notwithstanding their voluntary participation in the statutory information exchange and patent negotiation procedures. But where, as in Apotex's case, an applicant has made available to

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[17] The patent resolution provisions of H.R. 1548, 111th Cong. (2009), were substantially incorporated into the BPCIA's final text. *See* Carver, *An Unofficial Legislative History*, 65 Food & Drug L.J. at 802-06 (describing how the patent provisions of H.R. 1548 were incorporated into the final legislation).

the sponsor the information outlined in paragraph (*l*)(2)(A), the reference product sponsor has all the information needed to enforce its intellectual property rights, including "a copy of the application" and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." As such, mandating the notice of commercial marketing will in most, if not all, cases in which an applicant has provided the paragraph (*l*)(2)(A) disclosures, convey a windfall upon sponsors without providing any countervailing public benefit. In Amgen's case against Apotex, for example, not only did Apotex already provide Amgen with all the information Amgen needed to determine whether to litigate its intellectual property rights, but Amgen in fact already had undertaken to litigate all relevant patents, which Apotex's product was found not to infringe. The 180-day injunction therefore serves no purpose other than to preserve Amgen's exclusive market for an additional six months.

CONCLUSION

The judgment of the court of appeals should be reversed with respect to the questions presented in the petition by Sandoz and affirmed with respect to the question presented in the cross-petition by Amgen.

Respectfully submitted,

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February 17, 2017

RECORD AND BRIEFS

FILED
FEB 17 2017
OFFICE OF THE CLERK
SUPREME COURT, U.S.

Nos. 15-1039 and 15-1195

IN THE

Supreme Court of the United States

SANDOZ INC., PETITIONER,

v.

AMGEN INC., ET AL., RESPONDENTS

AMGEN INC., ET AL., PETITIONERS

v.

SANDOZ, INC., RESPONDENT

On Writs of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF FOR THE BIOSIMILARS COUNCIL AS AMICUS CURIAE SUPPORTING SANDOZ INC.

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BRIEF FOR THE BIOSIMILARS COUNCIL AS AMICUS CURIAE SUPPORTING SANDOZ INC.

INTEREST OF THE AMICUS CURIAE

The Biosimilars Council (the "Council"), a division of the Association for Accessible Medicines ("AAM"), represents the companies and stakeholder organizations working to develop biosimilar products for the U.S. pharmaceutical market.[1] Biosimilars are highly similar or interchangeable versions of branded biologic medicines licensed by the Food and Drug Administration ("FDA"), and an entity seeking FDA approval of a biosimilar is known as a biosimilar "applicant." A branded biologic in this context is known as a "reference product" and its license holder as the reference product "sponsor." Congress established an expedited FDA approval pathway for biosimilars in 2010 in the Biologics Price Competition and Innovation Act ("BPCIA").[2]

The Council's members aim to provide consumers with access to safe, effective alternatives to expensive biologic therapies. Biologic medicines now account for nearly 40% of annual drug approvals by the FDA. Bernard Munos, *2015 New Drug Approvals Hit 66-Year High!*, Forbes.com (Jan. 4, 2016),

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[1] The parties consented to the filing of this brief. No counsel for a party authored any part of this brief; no party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief; and no person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the brief's preparation or submission.

[2] Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 119 (2010).

http://www.forbes.com/sites/bernardmunos/2016/01/04/2015-new-drug-approvals-hit-66-year-high/#4ecaa3c11044. With annual U.S. spending on biologic drug therapies in the United States exceeding $100 billion,[3] and only a few biosimilars available on the U.S. market thus far, biosimilars offer the potential for tens of billions of dollars in health savings. And savings are not limited to consumers and private insurers: the federal government spends more than $5 billion each year on biologic drug therapies through such programs as Medicare and Medicaid.[4]

The Council and its members supported passage of the BPCIA and are deeply interested in its correct implementation and interpretation. To that end, the Council has participated in litigation as *amicus curiae* regarding the proper interpretation of the BPCIA, taking legal positions that reflect the position of the Council as an organization. The Council filed a brief in this case below and in support of Sandoz's petition for certiorari. The Council's parent organization, formerly named the Generic Pharmaceutical Association, has likewise frequently participated in litigation as *amicus curiae* regarding patent and regulatory issues affecting pharmaceutical manufacturers. *See, e.g., Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

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[3] *See* The Biosimilars Council, *The Next Frontier for Improved Access to Medicines: Biosimilars and Interchangeable Biologic Products* 14 (2015), *available at* http://www.biosimilarscouncil.org/pdf/GPhA-biosimilars-handbook.pdf.

[4] Pew Charitable Trusts, *Can Biosimilar Drugs Lower Medicare Part B Drug Spending?* (Jan. 3, 2017), http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2017/01/can-biosimilar-drugs-lower-medicare-part-b-drug-spending.

The Council's members have all sought or intend to seek FDA approval of biosimilar products through the BPCIA's abbreviated approval pathway. They are and will continue to be subject to the complex set of rules that govern approval and related patent litigation with biologic manufacturers. The Council and its members therefore have a strong interest in ensuring that the BPCIA is interpreted in a manner consistent with Congress's goal of expediting patient access to affordable versions of biologic therapies. That principle requires two conclusions here: *First*, the Federal Circuit was wrong to give biologic manufacturers an additional six months' market exclusivity beyond the already-generous twelve years the BPCIA expressly provides. *Second*, the Federal Circuit was right to hold that when a biosimilar applicant decides not to provide its confidential information to a biologic sponsor, the sponsor's sole remedy is the one set out in the statute: a patent-infringement action.

SUMMARY OF ARGUMENT

The BPCIA is a complex statute that was drafted over several years with extensive input from numerous federal agencies, legislators, and industry representatives. When Congress provided a 12-year exclusivity period in that statute, it meant 12 years, not 12½; when Congress omitted an injunctive remedy, its omission was no accident.

The BPCIA attempts to spur investment in cost-saving biosimilar products by creating a new abbreviated pathway for biosimilar approval—but only after the biologic product enjoys a 12-year period of exclusivity protection against biosimilar competition,

the longest such period in the world. Congress recognizes that marketing a biosimilar will sometimes raise patent issues, and it sought to lower the temperature of such patent litigation by creating a procedure to simplify it. The BPCIA creates strong incentives for biosimilar applicants to provide confidential, proprietary business information to sponsors voluntarily. That information exchange—known as the "patent dance"—can allow patent disputes to be resolved without the need to overwhelm courts with the kitchen-sink approach to litigation.

The BPCIA allows the parties to choose a two-phase process for patent litigation over a biosimilar: Phase I, limited to the patent issues that the parties decide to litigate shortly after a biosimilar application is filed, 42 U.S.C. § 262(*l*)(6), and Phase II, involving any remaining patents, *id.* § 262(*l*)(8). The BPCIA does not tie FDA approval to the resolution of patent disputes, as does the statute governing approval of generic small-molecule drugs ("Hatch-Waxman"), *see* 35 U.S.C. § 271(e)(4)(A). Rather, the BPCIA allows the parties to choose to sequence their patent dispute by providing different triggers for the litigation of Phase I and Phase II patents. But if the applicant chooses not to opt in to the patent dance, the statute permits immediate litigation of all patents. *See* Sandoz Br. 12-13.

Apparently unsatisfied with the provisions in the statute itself, respondents[5] seek rights and remedies that are nowhere to be found in the text of the BPCIA. First, respondents seek an additional 180-

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[5] "Petitioner" and "respondents" refer to the parties in the lead case, No. 15-1039.

day exclusivity period *in every case*: they contend that the applicant's advance notice of commercial marketing required by the statute cannot be effective until after biosimilar products receive FDA approval, so the applicant must *always* wait 180 days after approval before marketing. Second, they argue that the consequence for an applicant's failure to engage in the patent dance is not limited to the remedies set forth in the BPCIA itself (the sponsor's entitlement to file a patent-infringement action), but instead also includes the right to an automatic injunction ordering applicants to provide their confidential business information to sponsors. These claims find no support in the statute itself or its legislative history.

The BPCIA's multi-year history makes clear that, in light of the needed cost-saving benefits of abbreviated approval for biosimilars, Congress gave sponsors a period of exclusivity that is 12 years and 12 years only, extendable only based on pediatric research. Proponents and critics alike recognized that the period is 12 years in all cases; *no one* referred to the period as 12½ years, as respondents would have it.

Respondents base their interpretation not on the text or history, but on various inferences about how patent litigation ought to proceed. But those inferences are unfounded. Respondents have argued that notice of commercial marketing cannot be provided until after FDA approval to ensure that the second phase of patent litigation does not occur until after the FDA defines the right and scope of biosimilar manufacture and sale. But if Congress wanted to delay litigation until after final FDA licensure, it would not have created an early patent-resolution process

that begins just "20 days" after a biosimilar application is accepted for filing, 42 U.S.C. § 262(*l*)(2), which can occur *eight years* before licensure, *id.* § 262(k)(7)(A)-(B). Respondents have also argued that their interpretations of both the patent-dance and notice provisions are necessary to prevent "surprise" launches by biosimilar manufacturers, but this concern is simply baseless given the transparency of the biosimilar pipeline[6] and the FDA's clear communications regarding its biosimilar approval timeline.[7]

Properly interpreted, the BPCIA will spur investments in biosimilars and provide financial relief to consumers, insurers, and federal and state governments, which currently pay more than $100 billion per year for biologics. In contrast, respondents' interpretation upsets the careful balance struck by Congress between encouraging future investment in biosimilar production and protecting the investments made by biologic companies. Moreover, respondents' interpretation needlessly delays much-needed financial relief that biosimilar products offer. And with many biologics costing more than $50,000 *per year*

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[6] *See, e.g.*, IMS Institute for Healthcare Informatics, *Delivering on the Potential of Biosimilar Medicines* 11 (Mar. 2016), *available at* http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Documents/IMS_Institute_Biosimilar_Brief_March_2016.pdf (discussing the 41 biosimilars in the pipeline as of March 2016).

[7] *See* FDA, Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 Through 2017, at 3-4 (FDA Biosimilar Authorization Performance Goals), *available at* http://bit.ly/2ecO0Yw.

per patient to treat serious illnesses, this relief cannot come fast enough.[8]

ARGUMENT

I. THE BPCIA ALLOWS COMPETITION FOR BRANDED BIOLOGIC MEDICINES AFTER THE STATUTORY 12-YEAR EXCLUSIVITY PERIOD, AND NOTHING IN THE STATUTE OR ITS LEGISLATIVE HISTORY SUPPORTS AN EXTRA 6-MONTH EXCLUSIVITY PERIOD.

The BPCIA requires biosimilar applicants to "provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). The text cannot reasonably be read to restrict applicants from providing such notice before FDA approval. That reading would necessarily extend the biologic's market-exclusivity period to 12½ years in every instance, as respondents' counsel expressly told the district court.[9] But the BPCIA is quite clear on the market exclusivity enjoyed by sponsors: it states that the "[e]xclusivity for reference product" is "12 years." *Id.* § 262(k)(7). And in the one instance in which Congress wanted to extend this exclusivity beyond

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[8] U.S. Gov't Accountability Office, Report to the Ranking Member, Committee on the Budget, House of Representatives 19 Tbl. 4 (Oct. 2015), http://www.gao.gov/assets/680/673304.pdf.

[9] Tr. of Mot. Hrg. at 65, No. C 14-4741 RS, ECF No. 104 (N.D. Cal. Mar. 17, 2015) (PI Mot. Hrg.) ("**THE COURT**: . . . Is there any scenario under your reading of [the BPCIA] that would allow anyone, any subsection (k) applicant, to go to market in less than 12 1/2 years? **[AMGEN'S COUNSEL]**: There is not.").

the 12-year mark, it did so expressly, providing that when sponsors conduct pediatric studies at the Secretary's request, the exclusivity period is "deemed to be . . . 12 years and 6 months rather than 12 years." 42 U.S.C. § 262(m)(2)(A), (3)(A). Respondents attempt to rewrite the statute to allow *every* sponsor to enjoy "12 years and 6 months rather than 12 years" of exclusivity, arguing that Congress "intended the notice of commercial marketing and its 180-day period to follow FDA approval." Amgen Br. in Opp. 20. But the statute's text, structure, and legislative history provide no support for this proposition, which would undermine the access to lower-cost biologic therapies that the BPCIA was enacted to promote.

A. Congress Developed the BPCIA's Abbreviated Pathway To Address The Extraordinary Cost of Branded Biologic Therapies.

Biologic drugs offer incredible promise in providing life-saving therapies for some of the most difficult-to-treat illnesses (such as cancer, genetic diseases, and blood disorders), but to date they have come at extraordinary cost. As Congress was informed in 2007, the average daily cost of a biologic ($45) was more than 22 times the average daily cost of a traditional pharmaceutical ($2). *See Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 110th Cong. 125-128 (2007) (statement of Ed Weisbart, M.D., Chief Medical Officer, Express Scripts, Inc.); *accord* Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 Am. Health & Drug Benefits 469, 469 (2013). For that

reason, Congress was highly motivated in the BPCIA to create a pathway that would avoid unnecessary delay or uncertainty in bringing biosimilars to market.

Many biologics cost tens of thousands of dollars annually *per patient*. Congress was aware when it adopted the BPCIA that Herceptin®, used to treat breast cancer, cost $37,000 per patient annually, and Cerezyme® cost $200,000 per patient annually to treat Gaucher's disease. *See* Judith A. Johnson, Cong. Research Serv., *FDA Regulation of Follow-On Biologics* 1 (Apr. 26, 2010) (CRS 2010), *available at* http://bit.ly/2dTKKoX. That trend continues: several biologics covered by Medicare Part B cost the government more than $50,000 per beneficiary per year, and at least one costs the government nearly *half a million* dollars annually per beneficiary. U.S. Gov't Accountability Office, *Report to the Ranking Member, Committee on the Budget, House of Representatives* 19 Tbl. 4 (Oct. 2015) (GAO Report), *available at* http://www.gao.gov/assets/680/673304.pdf; *see also* Judith A. Johnson, Cong. Research Serv., *Biologics and Biosimilars: Background and Key Issues* 2 (Sept. 7, 2016) (CRS 2016), *available at* https://fas.org/sgp/crs/misc/R44620.pdf (both Soliri® and Vimizim® exceed $250,000 per patient annually).

Biologics prices have had a profound impact on overall healthcare costs. "Spending on small-molecule drugs is close to stagnant," W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 Iowa L. Rev. 1023, 1026 (2016), but U.S. spending on biologics has more than doubled in the past ten years, from about $40 billion in 2006 to $92 billion in 2013—a whop-

ping 28% of all U.S. drug spending even though the number of approved small-molecule drugs dwarfs the number of approved biologics, *see* Cong. Budget Office, *Cost Estimate, S. 1695, Biologics Price Competition and Innovation Act of 2007*, at 5 (June 25, 2008) (CBO, *Cost Estimate*), *available at* https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/costestimate/s16950.pdf; CRS 2016, at 2-3. Indeed, annual spending on biologics has grown by 10-20% each year, whereas spending on traditional pharmaceuticals has remained almost level and spending on hospital and physician services has increased only by single digits. *See id.* at 5; CRS 2016, at 2-3; John R. Thomas, Cong. Research Serv., *Follow-On Biologics: The Law and Intellectual Property Issues* 2 (Jan. 15, 2014) (CRS 2014), *available at* https://www.fas.org/sgp/crs/misc/R41483.pdf.

This impact is not limited to consumers or private insurers: Medicare has also experienced massive spending increases on biologics in recent years. Spending on biologics under Part D grew from $1.9 billion to $3.5 billion between 2009 and 2012. Surya C. Singh & Karen M. Bagnato, *The Economic Implications of Biosimilars*, 21 Am. J. Managed Care S331, S331 (2015). In 2013 just *three* new biologics were alone responsible for more than half of the $5.9 billion that Medicare and Medicare beneficiaries spent on new Part B drugs and for 15% of *all* spending on Part B drugs that year ($20.9 billion). GAO Report 15-16.[10] By 2014, Part B spending on just five biologics totaled nearly $5.5 billion. Pew Chari-

[10] Medicare Part B covers drugs administered by physicians, typically in a clinic, doctor's office, or outpatient facilities; Part D covers self-administered outpatient prescription drugs.

table Trusts, *Can Biosimilar Drugs Lower Medicare Part B Drug Spending?* (Jan. 3, 2017), http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2017/01/can-biosimilar-drugs-lower-medicare-part-b-drug-spending. The enormous costs of biologics are putting a drastic financial burden on federal insurance programs and their beneficiaries.[11]

These cost concerns are precisely what animated Congress to pass the BPCIA, with legislators and commentators from across the political spectrum acknowledging the need for an abbreviated approval pathway to bring relief to patients, insurers, and government insurance programs and to address the healthcare cost crisis. Congress sought to quantify the cost savings that could result from an abbreviated approval pathway for biosimilars (then-named "follow-on biologics") as early as 2007. *See* CBO, *Cost Estimate* 1-9.

Later, when the BPCIA and predecessor legislation were being debated, the President and Congress discussed the urgent financial need for an abbreviated biosimilar approval pathway. In its proposed budget released in February 2009, the Obama Administration noted that "[p]rescription drug costs are high and rising" and proposed "accelerate[d] access" with a "legal pathway for generic versions of biologic drugs." Office of Mgmt. & Budget, *A New Era of Re-*

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[11] Part B beneficiaries are required to pay 20% of their drugs' costs, totaling thousands (sometimes tens of thousands) of dollars each year for many beneficiaries who rely upon biologic drugs. GAO Report 18 (332,000 beneficiaries had cost-sharing responsibilities ranging between $1,900 and $107,000 in 2013). Yet the average Medicare beneficiary's annual income is just $23,500. *Id.*

sponsibility 28 (2009), *available at* http://www.washingtonpost.com/wp-srv/politics/budget2010/fy10-neweera.pdf. A diverse group of legislators likewise addressed the need for lower-cost options for biologic therapies. *See, e.g.*, 155 Cong. Rec. H12914 (daily ed. Nov. 7, 2009) (statement of Rep. Shuler) (discussing the "moral obligation to provide a safe and effective pathway of bringing competition that will benefit patients"); 155 Cong. Rec. S6793 (daily ed. June 18, 2009) (statement of Sen. Brown) ("Perhaps nowhere [is the need to bring down costs and increase access] more obvious than the area of biopharmaceuticals or so-called biologics. . . . With costs to biologics ranging anywhere from $10,000 to $200,000 per patient per year, biologic treatments pose a significant financial challenge for patients, for insurance companies, for employers who are paying the bills, and for Federal and State governments that are also paying the bills."); *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 7 (2009) (*Biologics and Biosimilars Hearing*) (statement of Rep. Eshoo) (noting the "vital future" in the field of biotechnology but noting that given the "very expensive" "cost of biologic treatments . . . the time has come to develop a pathway . . . for biosimilar products"); 155 Cong. Rec. S5636 (daily ed. May 7, 2009) (statement of Sen. Clinton) ("follow-on biologics" pathway necessary to "provide significant savings to patients, employers, and the government" on the order of "$14 billion over the next 10 years"); *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H.*

Comm. on Energy & Commerce, 111th Cong. 2 (2009) (statement of Rep. Pallone) ("If biologics are the future, then we should do everything we can now to control costs while aiding innovation, just like Hatch-Waxman did.").

Reports submitted to Congress by the Federal Trade Commission ("FTC") and CBO and considered at congressional hearings[12] confirmed the cost savings that Congress's proposed abbreviated pathway could bring. The CBO estimated $25 billion in cost savings over a ten-year period, including more than $6 billion in direct government expenditures through Medicare, Medicaid, and other programs. CBO, *Cost Estimate* 5. The FTC estimated biosimilar price discounts of 10 to 30 percent, noting that "[a]lthough not as steep a discount as small-molecule generic drugs, a 10 to 30 percent discount on a $48,000 drug product represents substantial consumer savings." FTC, *Emerging Health Care Issues: Follow-On Biologic Drug Competition*, at v (June 2009) (FTC, *Follow-on Biologic Drug Competition*), *available at* http://bit.ly/2e5Wy2m.

The same theme recurs throughout the legislative history: the urgent need to access the cost savings that biosimilars could bring was the key motivation for adopting the BPCIA in 2010.

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[12] *See, e.g.*, 155 Cong. Rec. D684 (daily ed. June 11, 2009); 155 Cong. Rec. D677 (daily ed. June 10, 2009).

B. The Legislative History Makes Clear That Sponsors Would Enjoy Exclusivity For 12 Years And 12 Years Only.

The longer the exclusivity period granted to biologic sponsors, the longer before consumers, insurers, and the government could access the much-needed savings offered by a biosimilar pathway. The duration of that exclusivity period therefore was critically important. The statute ultimately set the period at "12 years," not 12½.

The 12-year period was a hard-fought compromise. The Obama Administration proposed a seven-year exclusivity period.[13] Others suggested an even shorter five-year period.[14] Branded biologics industry groups, in contrast, advocated for a much longer 14-year period.[15] But the FTC warned that such a lengthy period was unnecessary to promote innovation.[16] Eventually, Congress adopted a 12-year exclusivity period, to run from the date of the biologic's licensure, irrespective of any patents.

When that 12-year period was being debated, not a single legislator or stakeholder was under the impression that every biosimilar would enjoy 12½ years of market exclusivity. Instead, opponents decried the "12-year" period as unfair, unnecessary, and un-

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[13] CRS 2010, at 3-4.

[14] *See, e.g.*, Alfred B. Engelberg et al., *Balancing Innovation, Access, and Profits—Market Exclusivity for Biologics*, 361 N. Engl. J. Med. 1917, 1919 (2009).

[15] Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 726-27, 735-36, 772 (2010).

[16] *See* FTC, *Follow-on Biologic Drug Competition* 25-46.

just,[17] while supporters applauded the "12-year" period.[18] Indeed, Representative Eshoo, whose proposed amendment containing a biosimilar pathway

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[17] *See, e.g.*, 155 Cong. Rec. S8187 (daily ed. July 28, 2009) (statement of Sen. Brown) ("Let's hope that we in Congress take a stand for fiscal responsibility, for common sense, and for the Americans we serve by ratcheting down the 12-year monopoly sweetheart deal that the big drug companies are peddling"); *Health Care Reform Roundtable (Part II): Hearing Before the S. Comm. on Health, Education, Labor & Pensions*, 111th Cong. 35 (2009) (statement of John Rother, Executive Vice President for Policy & Strategy, AARP) ("[W]e continue to have concerns—also echoed in the FTC report about the 12-year exclusivity period included in the Senate HELP Committee compromise."); 155 Cong. Rec. S7180 (daily ed. July 7, 2009) (statement of Sen. Brown) ("[I]t takes less than 2 years for the average brand-name biologic to recoup the R&D cost. Why are some of my colleagues advocating for a 12-year monopoly period?"); 155 Cong. Rec. S11465 (daily ed. Nov. 18, 2009) (statement of Sen. Sanders) (noting the need to "stop drug companies from having exclusivity for 12 years").

[18] *See, e.g.*, *Biologics and Biosimilars Hearing* 184-188 (statement of Jack W. Lasersohn, General Partner, Verticle Group) (arguing that "12 years" of exclusivity is necessary to "protect biologics pioneers," and the "seven-year" period advocated by others would provide insufficient protection); *HELP Approves Biosimilars Provision with 12 Years of Exclusivity*, FDA Week, July 17, 2009, 2009 WLNR 13664255 (biological industry organization praised the "12-year proposal," saying that "[w]ith this vote, the HELP Committee has embraced our long held belief that a minimum of 12 years of data exclusivity establishes a fair and reasonable period to ensure continued biomedical innovation and provide the benefits of competition"); *Makers of Plasma Protein Therapies Support Eshoo's Biosimilars Bill*, FDA Week, July 10, 2009, 2009 WLNR 13169335 (industry organization supporting "a brand biologics-friendly bill" referenced the exclusivity period "of 12 years from the date of first licensure" as the "best" way to protect patient access and innovator resources).

with a 12-year exclusivity provision was eventually incorporated into the House version of the BPCIA, said that "innovative drugs and biologics typically stay on the market for about 12 years before facing competition. My legislation maintains this level of protection for biologics." *Biologics and Biosimilars Hearing* 8.

The myriad references to a "12-year" exclusivity period were not merely a matter of rounding down. When earlier proposals included, for example, 14½ years of exclusivity for sponsors, coverage of the legislative developments characterized the period accordingly.[19] Likewise, when there was uncertainty about the exclusivity period offered under any particular proposal, those disputes were ventilated during the legislative process. *See, e.g.*, *Senate Democrats' Biosimilars Deal Falls Apart in Meeting*, FDA Week, July 10, 2009, 2009 WLNR 13169315 (discussing disagreement about whether a proposed bill provided 9 years or 12 years of exclusivity). But there was no disagreement about the exclusivity offered by the legislation that was eventually passed—respondents have not pointed to (and the Council has not found) a single mention of the BPCIA offering

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[19] *E.g.*, *Eshoo-Barton Biosimilars Bill Drops Unintended Botox Protection*, FDA Week, Mar. 13, 2009, 2009 WLNR 4803584 ("The upcoming bill, with its expected 14 1/2 years of market exclusivity for brand biologics, will offer a brand-friendly alternative to legislation introduced Wednesday (March 11) by committee Chair Henry Waxman (D-CA)."); *Nine Energy & Commerce Dems Urge Waxman to Mark Up Biosimilars Bill*, FDA Week, June 19, 2009, 2009 WLNR 11765201 ("Waxman's bill calls for up to five years of exclusivity for brand biologics, but the alternative bill, sponsored by Rep. Anna Eshoo (D-CA), calls for 14 1/2 years of exclusivity.").

12½ years of exclusivity before a biosimilar could begin marketing its approved product. This issue would not have gone unnoticed. If industry groups or legislators believed the BPCIA offered 12½ years, pro-biologics groups would have been trumpeting this victory, and pro-biosimilars groups and legislators would have been criticizing this compromise, just as both did regarding the "12-year" period that all interested parties understood the statute to provide. The lack of any mention, whatsoever, of a 12½-year exclusivity period in the legislative history or contemporaneous press reports is irreconcilable with the notion of a 12½-year period that applies in every case, as respondents seek.

C. An Additional 180 Days of Market Exclusivity Would Cost The Public Billions And Dampen Incentives For Biosimilar Development.

1. The BPCIA's 12-year exclusivity period is lengthy to begin with. It exceeds the biologic exclusivity period available in every other country that has created an abbreviated biosimilar pathway. Europe has the second-longest exclusivity period, generally providing for ten years of market exclusivity; Canada's biologic exclusivity period is eight years. Donna M. Gitter, *Biopharmaceuticals Under the Patient Protection and Affordable Care Act: Determining the Appropriate Market and Data Exclusivity Periods*, 21 Tex. Intell. Prop. L.J. 213, 229 (2013). Other countries (including Australia, New Zealand, Japan, and South Korea) permit just five or six years of market exclusivity for biologics. *Id.* at 231. In addition, the BPCIA's 12-year period is more than double the exclusivity period available for entirely new

small-molecule drugs under the Hatch-Waxman Amendments. *See* 21 U.S.C. § 355(j)(5)(F)(ii) (five-year exclusivity for new chemical entities). The Federal Circuit's categorical rule thus makes the BPCIA's more-than-generous exclusivity provision even longer, and brings the United States even more out of step with the rest of the world.

There is a reason why every other country on the planet provides a shorter exclusivity period than the United States: biosimilars offer potential savings of billions of dollars per year. As noted above, the astronomical costs of biologic products are placing extraordinary burdens on consumers, private insurers, and government programs. Biosimilars in Europe, which have developed for years under abbreviated approval pathways, are generally priced 15-30% lower than reference biologic products. Blackstone & Fuhr 24; Price & Rai 1028. Experts and commentators have estimated that near-term discounts in the United States will likely be between 10-35%, and brand biologics may likewise cut their prices to discourage patients from switching to biosimilars. *Id.* at 27; Singh & Bagnato 19; CRS 2014, at 17-18 (collecting estimates).

Given the high price of biologic therapies, near-term discounts of even 15-30% over a six-month period offer significant cost savings. Ten-year savings created by the BPCIA are estimated to be at least $25 billion and potentially as high as $250 billion.[20]

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[20] *See, e.g.*, CBO Estimate 5; Express Scripts, Inc., *The $250 Billion Potential of Biosimilars* (Apr. 23, 2013), http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars; *see also* Andrew W. Mulcahy et al., Rand Corporation, *The Cost Savings Potential of Biosimilar*

If every biologic is assured an extra six months of exclusivity, that shifts literally billions of dollars from patients, federal programs, and insurance premiums to biologic sponsors. For an individual Medicare Part B beneficiary responsible for thousands of dollars per year in cost-sharing payments for a biologic drug that costs $50,000 or even $200,000 per year, or for a patient with private insurance and similar cost-sharing obligations, the six-month savings could mean the difference between selecting and forgoing much-needed therapies for serious illnesses.

2. The Federal Circuit's rule would be at least as detrimental for biosimilar manufacturers and potential biosimilar manufacturers as it would be for consumers, insurers, and taxpayers. Developing and manufacturing biosimilars is particularly expensive and time-consuming—far beyond the cost and time to develop and manufacture generic small-molecule drugs. As the FTC reported in 2009, development of each biosimilar will cost between $100 million and $200 million and take between eight and ten years, in comparison with small-molecule generic drugs, "which typically take three to five years to develop and cost between $1 and $5 million." FTC, *Follow-On Biologic Drug Competition*, at iii.[21] These cost

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Drugs in the United States 7 (2014) ($44.2 billion), *available at* https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

[21] *See also* Price & Rai 1028 (European biosimilar manufacturers "have on average expended between $100 million and $250 million and seven to eight years in the reverse engineering necessary to bring these products to market," and the cost "is likely to rise" as harder-to-manufacture biologics "begin to dominate the market"); Singh & Bagnato S333 ("The average cost of clinical development for a biosimilar ranges from $40 million to $300 million, and development takes up to 5 years . . . .").

and time commitments are on top of the $250 million to $1 billion investment that is required for drug companies "to build, equip and qualify their own manufacturing facilities," *id.* at 14, which the FDA takes about four years to approve, *see* CRS 2014, at 15; *see also id.* ("In addition, the cost of materials to manufacture biologics may be 20 to 100 times more than chemical drugs.").

The extra six months of market exclusivity created by the Federal Circuit's rule might not, upon initial glance, seem significant. But for a company that has spent or is considering spending half a billion dollars to build an appropriate manufacturing facility and successfully develop a biosimilar, the need to recoup that investment is very real. As the FTC has observed, given the high costs of entering the biosimilars market, the number of potential entrants is limited. FTC, *Follow-On Biologic Drug Competition* 14-15. The Federal Circuit's creation of an additional six-month delay before these companies can begin to recover their substantial investments is likely to shrink the universe of potential candidates still further.

II. THE PURPOSE OF THE 180-DAY NOTICE RULE IS TO ALLOW PATENT LITIGATION TO PRECEDE LAUNCH, NOT TO MAKE THE PARTIES WAIT FOR A "FULLY-CRYSTALLIZED CONTROVERSY" BEFORE LITIGATION BEGINS.

The Federal Circuit justified its post-licensure rule based on its "belie[f]" that Congress intended the notice to follow licensure, "at which time the product, its therapeutic uses, and its manufacturing processes are fixed" because at that point there is a

"fully crystallized controversy." Pet. App. 21a.[22] But the court cited no basis in the text, structure, or legislative history of the statute for that belief, and there is every indication that Congress intended exactly the opposite.

A. Permitting Patent Litigation To Take Place Only When The Patent Controversy Is "Fully Crystallized" Is Inconsistent With The Statutory Structure And Would Be Nonsensical In Many Cases.

1. Respondents have argued that requiring that an applicant's commercial-marketing notice be provided only after FDA approval ensures that preliminary injunction motions are "based on the actual facts that matter" as "defined by the FDA license." Amgen Br. in Opp. 21. But Congress created a *pre-licensure* dispute-resolution process and built in substantial incentives for litigants to avail themselves of that process. *See Amgen, Inc. v. Apotex Inc.*, 827 F.3d 1052, 1059 (Fed. Cir. 2016); Pet. App. 71a-72a; *Biologics and Biosimilars Hearing* 9 (statement of Rep. Eshoo) (the early patent resolution process is intended to "ensure that all patent disputes involving a biosimilar are resolved before, and I emphasize before, the expiration of the data-exclusivity period"[23]). Congress also created "an artificial 'act of in-

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[22] "Pet. App." refers to the petition appendix filed in No. 15-1039.

[23] Representative Eshoo referred to a 12-year "data-exclusivity period," but in context it is clear that she was referring to the 12-year *market* exclusivity period during which the FDA is prohibited from approving a biosimilar version of a particular biologic, not the 4-year data-exclusivity period during which a biosimilar application cannot even be filed. The bill Representative Eshoo discussed, H.R. 1548, contained 12- and 4-year peri-

fringement'" that permits "infringement suits based on a biosimilar application prior to FDA approval and prior to marketing" if an applicant fails to engage in the patent dance altogether. Pet. App. 6a (citing 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6)). If Congress had intended patent litigation to occur only after there was a "fully crystallized controversy" post-licensure, it would not have permitted—indeed, encouraged—infringement lawsuits to be filed shortly after an applicant submits a biosimilar application and long before approval.[24]

Furthermore, the Federal Circuit's concern with the waste of resources that could result from patent litigation over products that may never obtain FDA approval or that may be changed during the approval process, Pet. App. 21a, is simply unfounded. Both Hatch-Waxman and the BPCIA intentionally encourage applicants to resolve patent issues after an application is filed but before FDA approval—after the patent dispute is sufficiently "crystallized" for a

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ods virtually identical to the ultimately-passed BPCIA. Pathway for Biosimilars Act, H.R. 1548, 11th Cong. § 101 (2009). *See generally* Erika Lietzan, *The Myths of Data Exclusivity*, 20 Lewis & Clark L. Rev. 91, 104 (2016) (noting the inconsistent usage of the terms "data exclusivity" and "market exclusivity").

[24] Amgen has argued that even if the controversy is sufficiently crystallized before licensure to be litigable generally, it is not until the FDA's licensure decision that the dispute is "fully crystallized" to permit a sponsor to seek preliminary injunctive relief. Amgen Supp. Br. 7-8. But injunctive relief is *already* available in pre-approval patent litigation under Hatch-Waxman and the BPCIA. *See* 35 U.S.C. § 271(e)(4)(B), (D). Congress would have had no reason to fear that a sponsor would be unable to establish the necessary elements for injunctive relief, such as irreparable harm to the sponsor itself, until the *biosimilar* has license in hand.

court to determine validity and infringement, yet before a patent owner could claim to have suffered any actual damages. That is why the BPCIA replicated what the Hatch-Waxman statute established more than thirty years ago—it created an artificial act of infringement so that the dispute could go to court and have a good chance of being resolved before a product is marketed.

2. Amgen itself argued before the district court that the extra six-month period would apply in *every* case. *See* note 9, *supra*. But post-licensure notice, followed by a mandatory additional 180-day stay on a biosimilar's launch, would be nonsensical in many instances. For instance, there may be no active patents left once a biosimilar application is filed. Indeed, many key patents that cover biologic drugs representing tens of billions of dollars in annual sales have expired or are set to expire within the next three years, and for many of these drugs no biosimilar applications have yet been filed. *See* Singh & Bagnato S332 ("In 2013, more than 70% of the spending on biologics was attributed to products with patents that have expired or will soon expire; 12 additional biologic product patents are scheduled to expire in the United States by 2020."). Or there may be no active patents remaining after Phase I litigation has taken place, if the biosimilar applicant has prevailed in that phase. Finally, in many instances patent protection for the biologic will expire by the end of the 12-year exclusivity period. Indeed, proponents justified the 12-year period as mimicking the patent protection historically enjoyed by branded

drugs after FDA approval.[25] In each of these situations, all that is left to do during the 180-day period is wait for the sake of waiting.

In other instances, prohibiting notice until after licensure would require years of needless delay, followed by an unnecessary scramble to resolve patent disputes between licensure and launch. Because an applicant's notice of commercial marketing triggers litigation on Phase II patents, permitting only *post*-licensure notice means that Phase II litigation could likewise occur only post-licensure if the applicant participates in the patent dance. As biosimilar development improves and biosimilar manufacturers begin filing applications sooner after the four-year data exclusivity period, then biosimilar companies that engage in the BPCIA's information-exchange and early-dispute-resolution process will likely resolve Phase I patent issues with five or more years left before market exclusivity ends. Under respondents' interpretation, the parties would then senselessly sit on their hands for half a decade or more before being able to initiate Phase II litigation—all while memories fade, evidence becomes stale, and time passes.

B. Precluding Notice and Phase II Litigation Before FDA Approval Would Deprive Biologics, Biosimilar Developers, And Investors Of Much-Needed Certainty.

Permitting notice (and thus Phase II litigation) only after a biosimilar applicant receives FDA approval would deprive biosimilars and biologics alike

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[25] *See Biologics and Biosimilars Hearing* 8 (statement of Rep. Eshoo).

of much-needed certainty of patent validity and infringement issues. Certainty is vital to investor confidence in the patent world—particularly for pharmaceuticals. Knowing, as early as possible, whether a sponsor's patents are valid and infringed permits companies (both branded biologics as well as biosimilar developers) to make additional investments in biotechnology; it also "enable[s] the investor to determine whether or not to continue to pursue the commercial implementation of the new technology and will enable the investor to determine better where to invest in the future of that technology." Norman L. Balmer, *An Innovator's Prospective on Judicial Management in the United States*, 9 Fed. Cir. B.J. 615, 618 (2000).

The need for early patent certainty was not lost on Congress. Almost four decades ago, Congress enacted a patent reexamination process specifically aimed at reinforcing "investor confidence in the certainty of patent rights" by allowing the PTO to "settle validity disputes more quickly and less expensively than the often protracted litigation involved in such cases." *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 602 (Fed. Cir. 1985) (citation omitted). In passing that legislation, Congress recognized that efficient resolution of validity issues would "promote industrial innovation by assuring the kind of certainty about patent validity which is a necessary ingredient of sound investment decisions." H.R. Rep. No. 96-1307, at 4 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6463. The early patent resolution framework adopted in the BPCIA was similarly enacted "to expedite patent litigation concerning biosimilar products in order to maximize certainty, and diminish the risk that innovators will be unnecessarily deterred

from offering those products to the public." *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, __ F. Supp. 3d __, 2016 WL 5420566, at *6 (D. Mass. Sept. 26, 2016); *see also id.* at *7 ("[U]ncertainty relating to whether [a biosimilar] infringes a valid [patent covering a biologic] could affect decisions by potential investors in both Celltrion and Janssen."); FTC, *Follow-on Biologic Drug Competition* 50 (noting commentators' views that the "certainty" of "a pre-approval patent resolution process . . . would enhance their drug development activities," because "smaller companies . . . are unlikely to attract investment funds without certainty").

A biosimilar company wishing to avoid a cloud of uncertainty hanging over its biosimilar medicines for years under the respondents' rule would be left with two choices: include all patents in Phase I litigation, or skip the patent dance altogether, thus triggering a sponsor's right to file an immediate patent infringement action asserting all active patents. Either outcome would eviscerate the benefits of a multi-phase patent litigation framework that Congress deemed efficient and appropriate. Yet that is precisely what the respondents' interpretation would encourage.

III. RESPONDENTS' CONCERNS ABOUT "SURPRISE" BIOSIMILAR APPLICATIONS OR LAUNCHES DO NOT SUPPORT ENFORCING THE BPCIA'S PATENT DANCE PROVISIONS WITH AN EXTRA-TEXTUAL AUTOMATIC INJUNCTION OR ADDING SIX MONTHS OF EXTRA EXCLUSIVITY PERIOD FOR ALL BIOLOGICS.

Amgen has argued that its interpretation of the BPCIA is necessary to protect against a surprise FDA filing and product launch by biosimilar applicants. But the biosimilar pipeline is significantly transparent: there is no reason to suggest that a stealth filing or launch has ever been or could ever realistically be an actual concern, and it would be nonsensical to adopt a countertextual interpretation of the statute based on such imagined pragmatic worries. Moreover, the notion that a biosimilar manufacturer would file secretly and launch at risk when patent issues remain to be adjudicated, solely for the sake of taking its brand-name competitor by surprise, is extremely unrealistic: the entire reason for creating the artificial act of infringement is that enormous potential damages are a powerful disincentive to a stealth launch.

A. Respondents' Proposed Injunctive Remedy For A Biosimilar Developer's Failure To Engage In The Patent Dance Is Not Necessary To Protect Against A Secret Filing Or Surprise Launch.

As Sandoz explains (at 13-17), Congress provided biosimilar applicants with a choice about how to proceed with patent litigation: engage in the patent dance and enjoy the ability to control the phasing of

patent litigation, or decline to engage in the patent dance and be subject to an immediate patent-infringement action by the biologic sponsor. This choice makes eminent sense: there may be many instances in which a biologic has no more patent coverage by the time a biosimilar application is filed. In such instances, a biosimilar applicant would neither want nor need to provide its confidential business information to its competitor. Sandoz Br. 51.

Respondents have argued that although the BPCIA expressly sets forth a sponsor's recourse for an applicant's failure to engage in the patent dance after filing its biosimilar application (the right to file a patent-infringement action immediately), the Court should read into the statute an additional remedy—an automatic mandatory injunction requiring the applicant to engage in the patent dance. Respondents suggest that this extratextual remedy is necessary because (1) without the information exchange process, an applicant will "keep secret the fact that it has filed an [application]" and thus a sponsor will have no way to know that the right to file a declaratory judgment action was even triggered, Amgen Supp. Br. 1; and (2) without the information obtained from the patent dance, biologics sponsors will not have sufficient information to draft a patent-infringement complaint, *id.* at 13; PI Mot. Hrg. 13-14. These purported concerns are illusory and provide no reason to rewrite the statute to create a remedy that Congress did not provide or even contemplate.

First, there is no information deficit regarding the filing of a biosimilar application or, indeed, the biologic and biosimilar development pipeline in general. Pharmaceutical companies are subject to various

regulatory requirements and market pressures that make the development and approval pipelines for biologics and biosimilars both robust and transparent. Interested observers can easily track the development of biologic and biosimilar medicines through clinical trial announcements that companies are required to register publicly with the FDA, and through investor presentations and disclosures that publicly held companies must provide in compliance with SEC regulations.

For example, under the Food and Drug Administration Modernization Act of 1997,[26] the FDA is required to maintain a public information registry on all "federally or privately funded clinical trials conducted under investigational new drug applications to test the effectiveness of experimental drugs for patients with serious or life-threatening diseases or conditions." Nat'l Institutes of Health, *History, Policies, and Laws*, ClinicalTrials.gov (Feb. 2, 2017), https://clinicaltrials.gov/ct2/about-site/history#CongressPassesLawFDAMA; *see also* 42 U.S.C. § 282(i). This registry allows the public to search for clinical studies according to a number of criteria, including the condition sought to be treated, the type of drug or "intervention" being studied, the sponsor or collaborator, and general search terms. For example, a search for "filgrastim," the drug in Amgen's Neupogen® product and Sandoz's Zarxio® product, produces results for various stages of clinical trials studying the drug, including the Phase III study of Sandoz's filgrastim product, which the site indicates was started in December 2011, received by the regis-

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[26] Pub. L. No. 105-115, 111 Stat. 2296 (codified in scattered sections of 21 U.S.C. §§ 301-81).

try on January 13, 2012, and completed in June 2013.

Publicly held companies are required to provide their investors and the markets with regular updates on pipeline products, often including detailed information on expected development, regulatory approval timelines for such products, and potential litigation risks. Consequently, biosimilar applicants commonly make public announcements of critical development stages and of submissions to the FDA.[27]

In addition, both public and private companies regularly detail their pipelines in presentations to investors and potential investors. These presentations provide a similarly robust look into the biosimilar pipeline, with detailed information regarding clinical trial status and expected filing dates. *See, e.g.*, Sandoz, *Meet Novartis Management Investor Presentation* 24 (May 2016), https://www.novartis.com/sites/www.novartis.com/files/2016-06-meet-the-management-3-sandoz.pdf (past and anticipated biosimilar filings); Cadila Healthcare Limited, *Investor Presentation* 15 (May 2016), https://zyduscadila.com/wp-content/uploads/2016/05/InvestorPresentation-May2016.pdf (biosimilar pipeline, including development status).

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[27] *E.g.*, Sandoz, Press Release, FDA accepts Sandoz application biosimilar filgrastim (Jul. 24, 2014), https://www.sandoz.com/news/media-releases/fda-accepts-sandoz-application-biosimilar-filgrastim; Coherus Biosciences, Press Release, Coherus Biosciences Announces Positive Topline 24-Week Treatment Phase Three Results For CHS-1420 (Humira® Biosimilar Candidate) In Patients With Psoriasis (Jan. 10, 2017), http://investors.coherus.com/phoenix.zhtml?c=253655&p=irol-newsArticle&ID=2236538.

Such announcements and presentations are important for public companies concerned about stock prices and providing transparent disclosures to investors, and for smaller or privately-owned companies that must obtain private financing to fund development activities. There is simply no incentive to keep such filings a secret, and the notion that an additional injunctive remedy for a biosimilar's failure to engage in the patent dance is necessary to protect a sponsor from the biosimilar's surprise filing is plainly inconsistent with the realities of the biopharmaceutical marketplace both today and when Congress passed the BPCIA.

Second, should biosimilar applicants decline to take part in the patent dance, biologic sponsors are fully capable of obtaining the information they need to pursue a patent-infringement action against applicants, just as Amgen did here. As the Federal Circuit correctly noted, all of the information that would be provided through the patent dance can be obtained through discovery in a patent-infringement action. Like anyone else preparing to file civil action, biologic sponsors must simply conduct a diligent and reasonable pre-filing investigation and include allegations that it has a good-faith belief will have evidentiary support after a reasonable opportunity for further discovery. Fed. R. Civ. P. 11.

Given the transparency of the biosimilar development pipeline based on federal regulatory requirements and the extensive information publicly available, obtaining sufficient information to draft a complaint is hardly an impossible task. Sponsors can search SEC disclosures, listen to investor and analyst calls, review conference presentations, and explore clinical trial information to determine

whether they have a good faith basis for alleging that one or more of their patents is infringed by an applicant. A sponsor can also request information about a biosimilar and its manufacturing process from an applicant through a "demand letter"; if the applicant refuses to provide such information, the sponsor can then file an infringement suit "on information and belief" in light of the applicant's failure to respond. *See Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1362-64 (Fed. Cir. 2000) (rejecting theory that patent plaintiffs must "obtain and set forth in their complaint facts showing infringement" when the plaintiff conducted a reasonable pre-filing inquiry, including a request for the defendant to disclose the method by which its product was made).

Respondents' further assertion that sponsors will have insufficient information about which claims to assert and thus "[v]alid claims will go unasserted," Supp. Br. 13, is likewise a false concern. "Infringement complaints are usually sparse and conclusory," merely alleging "that a defendant is directly or indirectly infringing a patent" and identifying the plaintiff's asserted patents. Fed. Judicial Ctr., *Patent Case Mgmt. Judicial Guide* 2-20 (2009). It is commonplace for a defendant to "not know which claims of the patents are being asserted against it" or even specifically "which of its products or processes are accused of infringing." *Id.* Nevertheless, "the patent holder is not required to do more" under our notice pleading standards. *Id.* It is equally commonplace for patent plaintiffs to assert initial patents and amend the complaint when new information is obtained in discovery. *See, e.g., 3Com Corp. v. D-Link Sys., Inc.*, No. C 03-2177 VRW, 2007 WL 949599, at *7 (N.D. Cal. Mar. 27, 2007) ("It is to be expected

that a patent holder may find other product designations that infringe as discovery progresses."); *SAP Aktiengesellschaft v. i2 Techs., Inc.*, 250 F.R.D. 472, 472 (N.D. Cal. 2008) (granting leave to amend to assert additional patent identified during discovery as infringed).

In short, biologic sponsors are not uniquely burdened in litigation simply because their competitors' confidential information may not be presented to them on a silver platter; instead, they are in the same position as every other patentee, and practically every other civil plaintiff, that litigates in federal court. There is simply no indication that Congress thought sponsors unable to bring patent lawsuits without the patent dance, and this nonexistent problem certainly cannot justify reading into the statute an injunctive remedy that artificially extends the 12-year monopoly.

Moreover, such a theory is inconsistent with both the text and overall structure of the statute. Congress made a biosimilar applicant's failure to provide its application to a biologic sponsor an artificial act of infringement that permits the sponsor to file a patent-infringement action immediately. 35 U.S.C. § 271(e)(2); 42 U.S.C. § 262(*l*)(9)(C). This would be a very odd remedy if Congress believed that sponsors lack sufficient information to bring a patent-infringement action absent the information provided during the patent dance. To the contrary, Congress recognized that in light of the realities of patent litigation, the right to bring an immediate patent-infringement action is an adequate remedy for an applicant's failure to engage in the patent dance.

B. Post-Licensure Notice Is Not Necessary To Protect Against A Stealth Launch.

Amgen has contended—and the Federal Circuit agreed—that a pre-licensure notice rule would encourage applicants to launch their products by surprise, with sponsors having no idea when commercial marketing will actually begin. Amgen Br. in Opp. 21; Pet. App. 21a. Amgen has also argued that without an automatic injunction for failing to provide notice, biosimilars will simply decline to give notice at all and take biologic patent holders and the courts by surprise by launching immediately upon FDA approval. Supp. Br. 1. But there is no reason to suggest that Congress thought a stealth launch has ever been or could ever be a concern.

First, as noted above, the biologic and biosimilar pipelines are robust and remarkably transparent. *See supra* pp. 28-30. Furthermore, absent a patent issue, biosimilar companies will generally want to launch as soon as they obtain approval so they can start recouping their investments immediately, and the FDA has been transparent about its approval timeline (within 10 months in 90% of cases[28]), leaving little question about a biosimilar's likely launch date. FDA approval itself is certainly not a stealthy matter; indeed, FDA issues a press release immediately upon approval of biosimilars, and the biosimilar applicants have done the same. *E.g.*, FDA, Press Release, FDA Approves First Biosimilar Product Zarxio, Mar. 6, 2015, http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm436648.htm; Sandoz, Press Release, FDA approves Sandoz Erelzi™ to treat multiple inflammatory diseases

[28] FDA Biosimilar Authorization Performance Goals 3-4.

(Aug. 30, 2016), https://www.sandoz.com/news/media-releases/fda-approves-sandoz-erelzitm-treat-multiple-inflammatory-diseases.

Second, to the extent a surprise launch is ever realistic, it would occur when there are no more patents to be concerned about—and when there is therefore no reason to delay six more months following notice to a sponsor.[29] Under those conditions, a failure to tell the biologic sponsor about licensure of the biosimilar before launching would raise no legitimate concerns—the biologic sponsor no longer enjoys monopoly protection, and the biosimilar applicant has a right to sell its product once the FDA licenses it. As respondents themselves stated, the 180-day notice period is intended to "ensure an orderly litigation process," Supp. Br. 5; where there can be no conceivable litigation following notice, even a hypothetical risk of a stealth launch poses no practical concerns.

Given the practical realities of the biosimilar pipeline and biosimilar companies' economic interests in resolving patent litigation before launch, Congress simply would not have credited respondents' purported worry about the risk of a surprise launch. There is simply no reason to contort the statute to solve this fictional problem.

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[29] The number of biologics not covered by patents is set to grow. *See* Blackstone & Fuhr 473 ("Between 2009 and 2019, $50 billion of the market value of biologics in the United States alone will lose patent protection.").

* * * * *

Congress did not extend biologic sponsors' monopoly for an additional six months past the 12 years the statute unambiguously provides. Nor did Congress silently authorize an injunctive remedy to combat a stealth launch that it had no reason to believe would ever occur.

CONCLUSION

The judgment of the court of appeals should be reversed with respect to the questions presented in Sandoz's petition and affirmed with respect to the question presented in Amgen's petition.

Respectfully submitted.

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February 17, 2017

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EF8

Court, U.S.
FILED
MAR 17 2017
OFFICE OF THE CLERK

IN THE
SUPREME COURT OF THE UNITED STATES

SANDOZ INC.,
Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED
Respondents.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
Cross-Petitioners,

v.

SANDOZ INC.,
Cross-Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF OF AMICUS CURIAE BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS CURIAE

The Biotechnology Innovation Organization ("BIO") is the principal trade association representing the biotechnology industry in all fifty states and abroad. BIO has more than 1,000 members, including businesses, biotechnology centers, and academic institutions.[1]

BIO members undertake research and development of biotechnological health care, agricultural, environmental, and industrial products, including innovative life-saving drugs as well as biosimilars. BIO's members range from Fortune 500 companies to research universities and small start-up companies. The majority of BIO's corporate members are development-stage companies that have yet to bring their first commercial product to market.

As one of the leading proponents for the creation of a biosimilar approval pathway that also maintained incentives for continued innovation, BIO

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[1] This brief reflects the prevailing views of BIO's members, but not necessarily the views of any individual member. The views expressed herein should not be attributed to BIO members Amgen Inc. or Novartis, the parent of Sandoz Inc. Neither Novartis, any party, nor counsel for a party authored this brief in whole or in part, and no monetary contribution to its preparation or submission was made by anyone other than BIO or its counsel. The consents of Petitioner and Respondents are being lodged with the Clerk of the Court concurrently with this brief.

has a strong interest in the proper implementation of this statutory scheme by the courts.

STATEMENT

When Congress enacted the Biologics Price Competition and Innovation Act of 2009 (BPCIA) its aim was to create an approval pathway for biosimilar biological medicines that would balance incentives for innovation with consumer interests. Pub. L. No. 111-148, 124 Stat. 119, 804, §7001(b)(2). The legislation was developed over four years through multiple proposals, hearings, debates, and negotiations. Congress received input from stakeholders having varied and often competing interests. The resulting bipartisan legislation represented a meaningful compromise among such interests, providing a less expensive approval pathway for biosimilars, balanced by effective mechanisms to protect innovators' intellectual property.

In *Amgen v. Sandoz*, however, a panel majority of the Federal Circuit interpreted the BPCIA's patent-dispute-resolution provisions as merely an optional set of procedures, which a biosimilar applicant could invoke or not in its discretion. This construction was contrary to the plain meaning of the text, the purpose

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[2] The BPCIA amended Section 351 of the Public Health Services Act by inserting new subsections (k) and (*l*), codified at 42 U.S.C. §262(k) and (*l*). It also amended the Patent Act, the Declaratory Judgment Act, and the Food, Drug and Cosmetics Act.

of the legislation, and the intent of Congress. As an active participant in Congressional negotiations and legislative developments at every step of the way, BIO is well-positioned to explain the background and history of what became the BPCIA.

A. Creating a Biosimilars Pathway.

In the early 2000s, the only regulatory pathway for generic medicines was under the Hatch-Waxman Act,[3] which authorized approval of generic versions of previously-approved drugs based on an Abbreviated New Drug Application (ANDA). Under this pathway, the generic manufacturer could rely on the innovator's prior FDA approval to establish the safety and efficacy of the generic drug, greatly reducing research and development costs and allowing it to offer products at lower prices. *See* 21 U.S.C. §355(j). By statute, these provisions applied only to products containing the "same" active ingredient as the originally approved drug. 21 U.S.C. §355j(2)(ii)(i).

This requirement effectively precluded the use of the ANDA pathway for approval of "generic" versions of biologics. Biologics are biomolecules that are produced in living organisms through recombinant DNA technology. Manufacturers use a wide variety of technologies to produce biologics. They make them in different cell lines derived from different species, they use different techniques to

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[3] The Drug Price Competition and Patent Term Restoration Act, Pub. L. No-98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §355.

insert genetic material into the cells, they employ proprietary expression systems to produce biologics in high volume, they grow the cells in unique culture media, they utilize different purification techniques, and more. The choices they make, and the dissimilarities among the manufacturing processes they employ, invariably affect the structural and functional properties of the final product. As a consequence, no two biologics could be expected to have the "same" active ingredient, as required by Hatch-Waxman's ANDA pathway.

In 2006, Congress began considering legislation to authorize the marketing of "biosimilars"—biological medicines that are highly similar to (though not the same as) previously approved biologics. One of the key issues Congress faced in creating this new approval pathway was to ensure an effective mechanism for resolving the complex patent issues that might affect the timing of when a biosimilar manufacturer could begin commercial marketing of a new biosimilar product in the United States.

B. Borrowing from Hatch-Waxman, But No Orange Book.

As a starting point for designing patent provisions in biosimilars legislation, Congress borrowed from the Hatch-Waxman Act. There, Congress had created a special procedure for resolving disputes over the validity and infringement of an innovator's patents prior to a generic product's market entry. This process required the holder of the New Drug Application (NDA) for a previously-

approved drug (the "sponsor") to submit information to the FDA identifying all patents claiming the drug or a method of using the drug, "and with respect to which a claim of patent infringement could reasonably be asserted" against a person who manufactured, used, or sold it. 21 U.S.C. §355(b)(1), (c)(2). The FDA was charged with publishing this information in a listing that has come to be called "the Orange Book." *Id.* at §355(j)(7)(A)(iii).

With respect to each Orange-Book-listed patent, a generic applicant was required to certify either the patent's expiration date, or that, in the applicant's opinion, the patent was invalid or would not be infringed by the manufacture, use, or sale of the proposed generic drug (a so-called Paragraph IV certification). *Id.* at §355(j)(2)(A)(vii)(IV). If the applicant made a Paragraph IV certification as to any listed patent, it was required to send the sponsor written notice explaining why each unexpired patent identified in the notice was invalid or not infringed. *Id.* at §355(j)2(B)(iii)-(iv). If the applicant did not provide a Paragraph IV certification as to one or more listed patents, the FDA would postpone approval of the drug until the patents expired.

If the applicant provided a Paragraph IV certification and the sponsor wished to sue on a listed patent, it was required to bring suit within 45 days after the notice. *Id.* at §355(j)(5)(B)(iii). If it did, FDA approval of the generic would be stayed automatically for 30 months to permit resolution of the patent issues. *Id.*

These provisions represented a compromise between innovators and generics. Importantly, they served to minimize the risk of marketplace confusion and disruption to patients and clinicians that would result if patent disputes were not resolved prior to the generic's commercial launch. If they were not, a generic might enter the market but then be sued for patent infringement, and a court would have to decide whether the generic product should be withdrawn. *See Hearing Before the Subcommittee on Courts and Competition Policy,* July 14, 2009 at 105-107 (BIO) (explaining therapeutic disruption and business uncertainty for both sponsors and applicants resulting from judicial determination of patent infringement by prematurely-launched biosimilar).

When Congress began crafting biosimilars legislation, it again undertook to fashion a procedure to assure timely resolution of patent disputes. The goals were to (i) avoid delaying biosimilar market entry due to patent litigation; (ii) provide certainty to applicants, sponsors of the previously approved biologic drug (referred to in the BPCIA as the "reference product sponsor"), and the public; and (iii) protect the intellectual property rights of patent owners, to preserve incentives for developing the next generation of innovative, life-saving therapies. *See Introduction Of The Pathway For Biosimilars Act,* 154 Cong. Rec. E401 (daily ed. March 13, 2008) (Statement of Rep. Eshoo).

Congress recognized, however, that it could not simply adopt the Hatch-Waxman patent-dispute-resolution procedures, including its reliance on the Orange Book, as the mechanism for identifying

relevant patents and litigating disputed ones before biosimilar product launch.[4] That is because both the regulatory approval scheme and the patent landscape for biologics is much more complex. Under the BPCIA pathway, a biosimilar product need not contain the "same" active ingredient as the reference product, it need only be "highly similar" to the reference product and have no "clinically meaningful" differences. BPCIA, §351(i)(2). This means that the biosimilar product might be "similar enough" to qualify for abbreviated approval, but "different enough" to avoid infringing a patent directed to the sponsor's product. This is one reason why patents on manufacturing processes play such a vital role in protecting the biologic innovator's intellectual property.

This created a dilemma: without access to an applicant's FDA submission (its "abbreviated Biologics License Application," or aBLA), and without knowledge of the manufacturing processes an applicant was using, a sponsor would be unable to identify which patents "could reasonably be asserted" against a particular biosimilar (the Hatch-Waxman standard). *See* 21 U.S.C. §355(b)(1). If the sponsor could not identify in advance which patents could

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[4] Neither the generics industry nor the biotechnology industry advocated for an Orange Book listing of biologics patents. The FDA, complaining that its oversight role regarding the Orange Book "can embroil the Agency in litigation," took no position on what provisions should be included to identify relevant patents. *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. 245 (2009).

reasonably be asserted against the applicant, how could patent issues be resolved prior to commercial launch of the biosimilar?

C. Designing A New Patent-Dispute-Resolution Procedure.

The BPCIA's solution for identifying relevant patents and litigating them prior to launch of a biosimilar is specified in subsection (*l*), entitled "Patents."

Unlike Hatch-Waxman, subsection (*l*) does not create a public listing of relevant patents, but instead establishes a private information exchange. It begins by requiring that the applicant provide the sponsor confidential access to the applicant's aBLA and information about its manufacturing processes. With the benefit of that information, the sponsor is then required to list all patents that could reasonably be asserted against the biosimilar product. The applicant can then list additional patents it believes could be asserted. Next, the sponsor and applicant exchange contentions regarding validity, enforceability, and infringement of the listed patents. These provisions emerged after a variety of other alternatives were proposed, debated, and rejected.

D. Early Legislative Proposals.

In 2006, Representative Waxman of California and Senator Schumer of New York introduced nearly identical bills, H.R.6257 and S.4016. These bills defined a biosimilars approval pathway and also included patent provisions. The patent provisions

were markedly different from those eventually enacted in the BPCIA.

Most notably, the Schumer/Waxman proposal would have created a mechanism to identify and resolve patent issues that gave the biosimilar applicant the ***option*** whether to initiate the procedure at all. Specifically, at any time, including at the initial stages of development," an applicant "may send a request" for patent information to the sponsor of the reference product. S.4016, §3(16)(A). The sponsor then "shall provide" to the applicant a list of all patents, including licensed-in patents, that the sponsor believes "relate to the reference product." Armed with that information, the applicant "may," but need not, send a notice challenging the validity, enforceability, or infringement of any listed patent.[5] Such notice would trigger a 45-day period for the sponsor to sue for infringement of the listed patent.

Subparagraph 16(E), "Discretion of Applicants," affirmed that under the Schumer/Waxman proposal, the bill's patent procedure was at the option of the applicant:

> A comparable biological product applicant may not be compelled, by court order or otherwise, to initiate the

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[5] *See* Krista Carver, et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food and Drug L. J. 671, 722 (2010) ("the applicant could have selected the patents it wished to challenge and could have excluded any others it did not desire to litigate").

> procedures set forth in this paragraph. The decision as to whether to invoke the procedures set forth in this paragraph is left entirely to the discretion of the applicant or prospective applicant.

The Schumer/Waxman proposal reflected the preference of the generics industry that biosimilars legislation allow the resolution of patent issues while the FDA is reviewing the aBLA, but provide for litigating "only those patent disputes that the generic company believes would delay its launch." *See Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 110th Cong. 119 (2007) (Barr Pharmaceuticals). Under this concept, patents not selected by the generic company would be litigated only after it "begins marketing," *id.*, a so-called "at-risk" launch.

The Schumer/Waxman proposal's one-sided patent-dispute-resolution mechanism got no traction in the House or the Senate. As Sandoz concedes, it "went nowhere." *See* Opp'n to Cross-Pet. for Writ of Cert.[6] In 2009, over Representative Waxman's objection, the House Energy and Commerce Committee instead reported H.R.1548, introduced by Representative Eshoo. The Eshoo bill, unlike the

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[6] Senator Schumer and Representative Waxman introduced similar bills in 2007 (S.623, H.R.1038) and 2009 (S.726, H.R.1427).

Waxman bill, specified that the applicant "shall provide" the sponsor a copy of the aBLA and relevant manufacturing information. It contained no language like that in the Schumer/Waxman proposal giving the applicant unfettered discretion to invoke the patent procedures.

E. The Bipartisan Senate HELP Committee Bill.

In the Senate, the focus turned to a bill, S.1695, containing very different patent provisions. It was introduced by Senator Kennedy in June, 2007. Unlike the Schuman/Waxman proposal, S.1695 was bipartisan; its co-sponsors included Democrats Kennedy and Clinton, and Republicans Hatch and Enzi (informally known as the "Gang of Four"). These senators worked collaboratively on biosimilars legislation over the next three years, meeting regularly among themselves and with stakeholders.

In September 2009, the HELP Committee reported a comprehensive health care reform bill that included biosimilars legislation substantially identical to S.1695. Carver, 65 Food Drug L.J. at 792-96, 803. The HELP bill was thereafter enacted as Subtitle A ("Biologics Price Competition and Innovation") of Title VII of the Affordable Care Act.

1. Patent Information Disclosure Requirements

The HELP Committee bill contained elaborate new procedures to identify relevant patents without reliance on an Orange Book. To ensure ample time

for resolving patent disputes, it permitted the applicant to submit its aBLA just four years after FDA approval of the sponsor's reference product, even though FDA approval could not be made effective until twelve years after licensure of the reference product. S.1695, §351(k)(7). To permit the parties to identify the patents that needed to be litigated, it created a private information exchange, the first step of which was requiring the applicant to provide the sponsor confidential access to the applicant's aBLA and manufacturing information. *Id.* at (*l*)(2)(A). The parties then were required to exchange of lists of relevant patents and their patent contentions. These provisions in S.1695 are substantially identical to the patent-dispute-resolution provisions enacted in the BPCIA.

The bill did not include any language to the effect that invoking the procedures was left to the applicant's discretion. The idea of making some of the information exchange permissive had been considered in the drafting of S.1695, but ultimately was discarded. In the summer of 2007, HELP Committee staff solicited comment from stakeholders on alternative "Discussion Drafts" of S.1695. One (No. 7574) gave the sponsor and applicant the ***option*** to notify each other of patents they deemed relevant; another (No. 7645) made those procedures mandatory. *See* Carver at 757. By the time S.1695 was introduced, the drafters had cast aside the optional procedure in Discussion Draft 7574 in favor of the mandatory procedure that appears in the BPCIA. *Id.*

2. Two Phases of Patent Litigation

The HELP Committee bill specified not one, but two phases of pre-launch patent litigation following the information exchange. This approach was unique to S.1695, and was included in the BPCIA.

In brief, after the parties have exchanged their patent contentions, the BPCIA requires negotiations over which listed patents would be the subject of an "Immediate Patent Infringement Action" under §351(*l*)(6)) ("phase-one"). If the parties cannot agree, they are to exchange lists of patents they propose for immediate litigation, subject to an important exception: the applicant has the right to limit the number of patents to be litigated in phase-one to as few as one. §(*l*)(5(B)(ii)(II). All other listed patents are deferred, and, in general, cannot be asserted until a second phase of pre-launch patent litigation. The phase-two litigation is triggered only when the applicant sends the sponsor a "notice of commercial marketing" at least 180 days before the date of first commercial marketing of the licensed biosimilar. *Id.*, §(*l*)(8)(A). *See* S.1695 at 21-24, 26.

This unique procedure represented the HELP Committee's partial accommodation of views advocated by the generics industry. As noted above, the generic manufacturers would have preferred to have the right to choose which patents a sponsor could assert prior to biosimilar market entry and which it could not. *See* 110th Cong. 119 (Barr Pharmaceuticals).

The procedure set out in S.1695 and adopted in the BPCIA gave the applicant significant control over the timing and scope of patent litigation prior to market entry. If it chose to do so, it could limit phase-one litigation to a single patent. It would face the sponsor's assertion of additional patents later, but the applicant could defer phase-two litigation until as late as six months prior to launch. Although the phase-two procedure authorized the district court to grant a preliminary injunction to block market entry, the sponsor had no guarantee the court would do so.

3. Penalty Provisions.

Another feature of the HELP Committee bill (enacted in the BPCIA), was its inclusion of provisions penalizing a party for non-compliance with the patent-dispute-resolution requirements. For example, once the parties narrowed the list of patents for "immediate" litigation, the sponsor had to sue on the listed patents within 30 days, or else its recovery in any later-filed patent suit would be limited to a reasonable royalty. §(*l*)(6); BPCIA, §7002(c)(1)(B), 35 U.S.C. §271(e)(6)(A) and (B). Also, if the sponsor failed to identify a relevant patent in its original patent list, the sponsor would forfeit the right to assert the patent at all in a BPCIA infringement suit against the biosimilar product. *See* 35 U.S.C. §271(e)(6)(C).

The HELP Committee bill also addressed the possibility that an applicant might fail to comply with its obligations, such as the requirement of providing confidential access to its aBLA and manufacturing information. Such failure would give the sponsor the right to sue immediately for a declaration of patent

infringement on certain listed patents. §(*l*)(9)(C). These provisions created incentives for both parties to comply with the BPCIA's requirements, minimizing the need for judicial intervention to enforce them.

SUMMARY OF ARGUMENT

1. The information disclosure requirement in §(*l*)(2)(A) of the BPCIA is mandatory. It is the critical first step in an integrated patent-dispute-resolution process applicable to any manufacturer electing to take advantage of the BPCIA's abbreviated regulatory pathway for biosimilars. When Congress directed that a biosimilar applicant "shall provide" its application and manufacturing information to a reference product sponsor, it chose those words carefully, and it meant what it said. The BPCIA's information disclosure requirement must be enforced as written, else the carefully crafted balance achieved by the legislation will be upended.

2. Subsection (*l*)(8)(A) of the BPCIA likewise is mandatory. It is the triggering mechanism for phase-two litigation, creating a minimum six-month window during which a sponsor can assert all relevant patents and seek a preliminary injunction to block biosimilar market entry. The 180-day notice cannot be sent before FDA approval, both as a matter of statutory language and because until then the biosimilar product, its manufacture, and its intended uses remain subject to change. This requirement does not necessarily extend the sponsor's 12 years of data exclusivity for newer products, because there is nothing to preclude the FDA from issuing tentative approval, thereby satisfying the predicate for a 180-

day notice, before such approval becomes effective at the end of the 12-year period.

ARGUMENT

I. THE FEDERAL CIRCUIT MISINTERPRETED THE BPCIA IN HOLDING THAT A BIOSIMILAR APPLICANT COULD ELECT NOT TO DISCLOSE ITS APPLICATION AND MANUFACTURING INFORMATION.

The Federal Circuit's decision fundamentally misinterpreted 42 U.S.C. §262(*l*)(2)(A) as merely one step in an ***optional*** patent-dispute-resolution procedure that a biosimilar applicant could choose to invoke or not. The text of the disclosure requirement, the statutory context in which it appears, the structure of the BPCIA as a whole, and the legislative history and purpose all show the contrary.

A. The Plain Meaning of "Shall Provide" is that the Applicant's Disclosure Obligation is Mandatory.

In drafting the disclosure requirement set forth in §(*l*)(2)(A), Congress chose familiar words with a familiar meaning. By using the words "shall provide," Congress expressed its clear intent that the applicant's disclosure be mandatory. As this Court recently observed:

> Unlike the word "may," which implies discretion, the word "shall" usually connotes a requirement. Compare

> *Lexecon Inc.* v. *Milberg Weiss Bershad Hynes & Lerach*, 523 U. S. 26, 35 (1998) (recognizing that "shall" is "mandatory" and "normally creates an obligation impervious to judicial discretion"), with *United States* v. *Rodgers*, 461 U. S. 677, 706 (1983) (explaining that "[t]he word 'may,' when used in a statute, usually implies some degree of discretion").

Kingdomware Techs. Inc. v. United States, 136 S. Ct. 1969, 1977 (2016) (internal citations omitted)

In this case, Congress made its intent doubly clear, using "shall" in juxtaposition with the word "may" in the very same paragraph. 42 U.S.C. §262(*l*)(2)(B). *See Life Tech. Corp. v. Promega Corp.*, (S. Ct. 2017) (slip op. at 5), citing *United States v. Williams*, 553 U.S. 285, 294 (2008) ("[A] word is given more precise content by the neighboring words with which it is associated.") To give meaning to Congress's word choice, there must be a difference between §(*l*)(2)(A) and §(*l*)(2)(B): the first is mandatory, the second is permissive. *See Anderson v. Yungkau*, 329 U.S. 482, 485 (1947) ("[W]hen the same Rule uses both 'may' and 'shall', the normal inference is that each is used in its usual sense—the one act being permissive, the other mandatory."); *Lopez v. Davis*, 531 U.S. 230, 241 (2001) ("Congress' use of the permissive 'may' in §3621(e)(2)(B) contrasts with the legislators' use of a mandatory 'shall' in the very same section.") The Court's inquiry could properly end here. *Barnhart* v. *Sigmon Coal Co.*, 534 U. S. 438, 450 (2002); *King v. Burwell*, 135 S. Ct. 2480,

2489 (2015) ("If the statutory language is plain, we must enforce it according to its terms.")

B. The BPCIA's Structure as a Whole, and the Role that §(2)(A) Plays Within It, Confirm the Plain Meaning of the Text.

The plain meaning of "shall provide" is reinforced when the words are considered in the context of the BPCIA's patent provisions as a whole. The entirety of subsection (*l*) of the BPCIA is a coherent step-by-step process for resolving patent disputes prior to commercial marketing of the biosimilar. Allowing biosimilar applicants to "opt out" of their disclosure obligation would defeat the essential purpose of the patent-dispute-resolution scheme.

The BPCIA's disclosure requirement is the critical first step in the required process. As discussed above, Congress deliberately departed from the approach used in Hatch-Waxman. Under Hatch-Waxman, the universe of patents a sponsor can list and assert pre-launch are only those that cover its own drug or use of the drug, 21 U.S.C. §355(b)(1). This means they can be identified by the sponsor without needing access to any information from the applicant.

By contrast, under the BPCIA, the sponsor must list all patents that "could reasonably be asserted" on account of the applicant's making, using or selling the biosimilar product. 42 U.S.C. §262(*l*)(3)(A). The sponsor's ability to create this list depends on its access to information describing the biosimilar product, its properties, and the processes

by which it is manufactured. If the applicant were free to withhold that information, there would be no way a sponsor could know what patents can and should be litigated pre-launch, and the BPCIA's patent-dispute-resolution scheme would fail to accomplish its purpose.

Under the Federal Circuit's interpretation, there is no assurance that any patent disputes will be resolved prior to market entry. The FDA does not disclose the filing of an application; the statute relies on the applicant to contact the sponsor and provide confidential access to its application once the FDA accepts it for review. If the applicant has discretion to "opt out" of the subsection (*l*) procedures, it could avoid making any disclosure to the sponsor and simply launch at risk immediately after FDA approval.

The gamesmanship that this interpretation encourages would be compounded if the applicant could also "opt-out" of the 180-day-notice of commercial marketing required by §(*l*)(8)(A), as Sandoz urges. If Sandoz were right, the sponsor might not learn of the launch date until the day the biosimilar manufacturer announces it. The sponsor would then have to scramble to seek a preliminary injunction pursuant to 35 U.S.C. §§271(a) and 283 after commercial sales have already begun.

The BPCIA was designed as an abbreviated pathway, not a speedway for "at-risk" launches of biosimilars. Congress scarcely envisioned that the rollout of a new biosimilar product would be accompanied by the sponsor's emergency motion for

an order blocking commercial sales, filed under extreme time pressure and (assuming the applicant also "opted-out" of §(*l*)(2)(A)), with little or no information about the biosimilar product or its manufacture on which to base a claim of patent infringement.

This is not the orderly presentation and resolution of patent disputes that the BPCIA was meant to ensure. Other provisions of the statute underscore Congress's purpose. While the BPICA prohibits the FDA from effectuating its approval of a biosimilar product until 12 years after the reference product was first licensed, it allows the applicant to file its application just 4 years after such licensure. This lengthy period between filing of the application and market entry of the product was designed to provide ample time for the parties to litigate and resolve patent disputes prior to product launch.

Not only is the information disclosure requirement critical to the identification of relevant patents, it is also vital to the sponsor's ability to assert them. *See Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 208 (2009), (AIPLA Testimony) (opposing the Waxman bill because "the reference product holder has no ability under [its] terms to obtain information sufficient to provide a good faith basis to make infringement allegations under Rule 11 of the Federal Rules of Civil Procedure"). In short, absent mandatory information disclosure, the patent-dispute-resolution mechanism in the BPCIA simply would not work.

C. The Background and History of the BPCIA Bolster the Natural Reading of §(*l*)(2)(A).

Any uncertainty as to the meaning of §(*l*)(2)(A) falls away when the history of the legislation is considered. *See Life Technologies*, slip op. at 10 (interpreting 35 U.S.C. §271(f) and explaining that "[t]he history of § 271(f) bolsters our conclusion"). The members of the Senate HELP Committee who drafted the Senate bill enacted as the BPCIA were keenly aware of the difference between permissive information-exchange procedures invoked at the discretion of a party and mandatory information-exchange procedures. They carefully and mindfully chose the latter.

The evolution of biosimilars legislation shows that if Congress had wanted to give applicants discretion as to whether to invoke statutory patent-dispute-resolution procedures, it knew how to do so. *See, e.g.*, S.4016, §3(16)(A), (B), and (E) (providing that the decision whether to invoke these procedures was left "entirely to the discretion of the applicant"), discussed at pp. 8-10, *supra*. No such language was included in the BPICA.

Congress clearly knew the difference between "shall provide" and "may provide." As discussed above, in 2007 the Senate HELP Committee staff circulated for comment alternative Discussion Drafts of what became S.1695: one made the exchange of

patent lists optional for both parties, while another made the exchange mandatory. *See* p. 12, *supra*.[7]

A bipartisan consensus of the HELP Committee's members concluded that a mandatory patent-dispute-resolution procedure would best effectuate the goals of the legislation while balancing competing interests of stakeholders. Biosimilar manufacturers always had the option of submitting a full Biologics License Application supported by clinical data establishing safety and efficacy of their own biological product. But if they elected to take advantage of the subsection (k) abbreviated pathway, they had to accept both the benefits and the burdens.

The benefits to a biosimilar applicant were many. Using the subsection (k) pathway would save them hundreds of millions of dollars in clinical development costs. In addition, the new patent-dispute-resolution provisions allowed them to resolve patent issues before commercial launch, minimizing patent risk without the downside of Hatch-Waxman's 30-month stay of FDA approval. The procedure forced sponsors to list, for the benefit of applicants, all patents that could reasonably be asserted against the

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[7] The Senate HELP Committee did not produce a report on the proposed biosimilars legislation, but the House Committee on Energy and Commerce did, as part of its report on comprehensive health care reform legislation. The House Report characterized the biosimilar patent provisions as "establish[ing] new processes for identifying patents that might be disputed" and "a multistep patent resolution process." H.R. Report 111-299, pt. 1, at 742 (2009). The Report did not suggest that any part of this process was left to the applicant's discretion.

biosimilar, including manufacturing process patents, another advantage over Hatch-Waxman. In addition, unlike Hatch-Waxman, the BPCIA required that sponsors provide applicants, in advance of any litigation, their infringement and validity contentions as to all listed patents, enabling the applicant to make an informed choice about what patents it might challenge. And the BPCIA gave applicants significant control over the timing and scope of patent litigation, including the right to limit the sponsor to asserting only one patent in phase-one litigation.

In its briefing below, Sandoz complained that the BPCIA's patent-dispute-resolution procedure would take too long; it preferred the expediency of immediate litigation because Amgen's exclusivity period for the reference product had expired. Def.-Appellee Br. at 13, 35-36, *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015). But this is a short-term issue. For newer reference products, biosimilar applicants will have the opportunity to submit their applications, and thereby trigger the BPCIA's patent-dispute-resolution process, years before the exclusivity period ends. In view of the many advantages the process provides to applicants, it is unlikely that Sandoz's timing concern in this case will present a recurring problem for future applicants.

The BPCIA's patent-dispute-resolution mechanism was meant to benefit sponsors as well. Importantly, it gave them access to information about the biosimilar product and its manufacture, as was needed to allow them to enforce their patents, including manufacturing patents, prior to biosimilar market entry. The statute thus provided a means to

protect sponsors' intellectual property and avoid the market disruption and uncertainties that would come with at-risk launches of biosimilars.

The Federal Circuit's decision unfairly shifts the benefits of the patent provisions to applicants. As Judge Newman wrote below in dissent, "[t]he BPCIA reflects an explicit balance of obligations and benefits. When a beneficiary of the statute withholds compliance with provisions enacted to benefit others, the withholder violates that balance." Pet. App. 40a.

D. By Specifying One Consequence of an Applicant's Non-Compliance with the BPCIA's Patent-Dispute-Resolution Procedures, Congress Did Not Thereby Confer on Applicants the Right to "Opt Out" of Them.

While the panel majority acknowledged the plain meaning of "shall provide," it decided that an applicant could elect to ignore §(*l*)(2)(A) because the legislation specified "consequences" for such failure. Pet. App. 15a. The panel misread the applicable provisions and misunderstood their purpose.

The Federal Circuit mistakenly treated 35 U.S.C. §271(e)(2)(C)—the creation of an artificial act of infringement to permit suit—as a remedy for an applicant's failure to disclose the required information under §(*l*)(2)(A). It does no such thing. Section 271(e)(2)(C) specifies that the act of infringement is submission of the application, not the applicant's failure to satisfy its disclosure obligation;

indeed, by that point in the process, the artificial act of infringement has already occurred.

The reference to §(*l*)(2)(A) in §271(e)(2)(C)(ii) was necessary because for patent litigation to proceed, the artificial act of infringement must be tied to specific patents. Ordinarily, once the applicant has provided the §(*l*)(2)(A) information, the sponsor will have created a patent list, and §271(e)(2)(C)(i) will permit the sponsor to assert its listed patents, either in phase-one or phase-two. But where the sponsor never had access to the applicant's information and therefore could not be expected to have prepared a patent list, §271(e)(2)(C)(ii) provides a back-up. It defines the universe of patents that the sponsor can assert pre-launch as those that could have been identified had it created such a list. This is not a ***remedy*** for failure to provide the §(*l*)(2)(A) information; in no way does it redress that omission.

For the same reason, the Federal Circuit erred when it read §271(e)(4) as providing the "only remedies" for an applicant's failure to provide its application and manufacturing information. That section refers to the "only remedies" that may be granted for the artificial "act of infringement"—remedies like delaying approval, enjoining sales, etc.—but, as explained, an applicant's failure to provide the §(*l*)(2)(A) information is not an act of

infringement at all. The Government makes the same mistake. U.S. Br. at 17.[8]

The legislative history helps explain the reason for these provisions. Congress was aware of concerns raised by stakeholders that one or the other party might disregard its information exchange obligations, and it addressed those concerns by inserting various provisions to penalize and discourage non-compliance by either party. *See* pp. 11-14, *supra*. Contrary to the lower court's ruling, at no time in the course of Congress's developing the BPCIA did anyone suggest that including penalties or stating consequences for non-compliance would thereby convert statutory mandates into options. Rather, the provisions were added to give teeth to the statutory requirements, creating disincentives for non-compliance and minimizing the prospect that courts would need to intervene to enforce them.

The Federal Circuit did not cite any authority that a statutory mandate becomes discretionary if

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[8] The Federal Circuit's reasoning is also internally inconsistent. The court described §271(e)(4) as reciting the "only remedies" for non-compliance with §(*l*)(2)(A). Yet it then described the sponsor's right to bring a declaratory judgment action under §(*l*)(9)(C) as an additional remedy for non-compliance. The sponsor's right to sue for a declaratory judgment, moreover, does nothing to remedy the harm of the applicant's non-disclosure: it simply allows the sponsor to seek a declaratory judgment on a subset of its patent, excluding manufacturing patents. Not only are the latter patents often the most valuable, but the applicant's non-compliance with §(*l*)(2)(A) effectively prevents the sponsor from asserting them at all.

Congress specifies consequences for its breach. Innumerable federal statutes impose penalties or sanctions for failing to comply with statutory requirements. Our criminal laws, for example, impose fines and other punishments, yet no one would suggest that this gives the criminal the option to break the law. Similarly, our tax laws provide for penalties and fines, but they do not give taxpayers the option to choose between the penalty and the tax. The list could go on.[9]

Alternatively, the Government argues that there is no "private cause of action" to enforce the BPCIA's mandates. U.S. Br. at 20-24. But there was no reason for Congress to create a special BPCIA cause of action to enforce the patent-dispute-resolution procedures already required by the statute. The first step of information disclosure is essential to fulfilling the statute's purpose, and to allow an applicant to flout the rules would undermine the

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[9] Citing *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436, 442 (2016), the Government argues that even where a statute creates a mandatory rule, the mandatory language does not furnish Congressional guidance about what consequence should follow. The Government's reliance on *State Farm* is misplaced. This Court there ***agreed*** that Congress's use of "shall" "creates a mandatory rule . . . [the actor] must follow." *Id.* at 442. The Court then rejected petitioner's claim that the consequence of non-compliance was a harsh forfeiture, *id.* at 442-443, and instead interpreted the rule in light of its context and statutory purpose, the same approach that should guide the Court here. *Id.*

entire process created by Congress.[10] The Government concedes that a sponsor has the right under §(*l*)(9)(C) to bring a declaratory-judgment action to establish infringement of certain categories of patents. There is no reason why a district court cannot grant ancillary relief in such an action to compel compliance with §(*l*)(2)(A), whether in the exercise of its inherent equitable power or pursuant to the All Writs Act, 28 U.S.C. § 1651(a), to enable the sponsor to identify *which* patents have been infringed.

II. THE FEDERAL CIRCUIT CORRECTLY HELD THAT THE BIOSIMILAR APPLICANT'S 180-DAY NOTICE OF COMMERCIAL MARKETING AFTER FDA LICENSURE IS MANDATORY.

The Federal Circuit correctly interpreted 42 U.S.C. §262(*l*)(8)(A) as requiring the biosimilar applicant to provide notice of commercial marketing to the sponsor after FDA approval and no later than 180 days before commercial marketing of the biosimilar product. This mandatory notice is the essential trigger for phase-two litigation.

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[10] The applicant's information-disclosure obligation is balanced by strict rules limiting who among the sponsor's attorneys can have access to confidential information, and restricting its use to specified purposes. 42 U.S.C. §262(*l*)(1)(A). Under the Government's theory, an applicant would be unable to obtain judicial relief to enforce the sponsor's confidentiality obligations. Surely this cannot have been Congress's intent.

The first phase of litigation, as discussed above, provided the applicant the ability to limit a sponsor's initial assertion of patents to as few as one. In the second phase, Congress gave the sponsor the right to assert all patents excluded from the first phase, and to seek a preliminary injunction against commercial launch of the biosimilar product based on infringement of any listed patent. As the Federal Circuit recognized, this "provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product." Pet. App. 21a.

Like the applicant's disclosure obligation, its notice of commercial marketing is integral to the entire patent scheme. Simply put, it is the opening bell for phase-two litigation. Subsection (*l*)(8)(A) must be enforced in accordance with its terms to maintain the careful balance struck by Congress between the interests of innovators and those of biosimilar applicants.

A. The Applicant's 180-Notice of Commercial Marketing is Mandatory.

Subsection 262(*l*)(8)(A) is mandatory: "[the] applicant ***shall provide*** notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing" of the licensed biological product. Sandoz has shown no reason why this Court should override the plain meaning of the text.

For this second phase to work, the timing of the biosimilar's launch must be known to the sponsor. To obtain preliminary injunctive relief, the sponsor bears

the burden of demonstrating "imminent risk of irreparable harm." *See Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008) (preliminary injunction requires a clear showing that party is "likely to suffer irreparable harm in the absence of preliminary relief"); *O'Shea v. Littleton*, 414 U.S. 488, 502 (1974) (irreparable harm entails showing "the likelihood of substantial and immediate irreparable injury"). The 180-notice requirement provides the needed certainty and urgency for a court's preliminary injunction analysis.

Subsection (*l*)(8), read as a whole, makes that clear. Subparagraph (8)(B) focuses entirely on the sponsor's right to request a preliminary injunction "prohibiting the [biosimilar] applicant from engaging in the commercial manufacture of sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement." §262(*l*)(8)(B). Subparagraph (8)(C) requires in addition that, should the sponsor seek a preliminary injunction, both parties "shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion." §262(*l*)(8)(C). The minimum 180-day period from the applicant's notice to the date of commercial marketing was designed as a window within which the sponsor could establish its need for and entitlement to preliminary injunctive relief.

The express provisions of §(*l*)(8), and the context in which they appear, evidence Congress's intent to devise an orderly litigation process, not one that would require a sponsor to race into court on short notice seeking an emergency temporary-

restraining-order when the biosimilar applicant suddenly announces a launch date. As this Court has taught, courts must interpret statutes "'as a symmetrical and coherent regulatory scheme' and 'fit if possible, all parts into an harmonious whole.'" *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

Congress did not design the BPCIA's patent provisions to facilitate at-risk launch, the timing of which would be known only to the applicant. Rather, Congress sought to "ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." 111th Cong. 9 (statement of Rep. Eshoo).

Sandoz erroneously argues that the 180-notice of commercial marketing cannot be mandatory because there may be instances when there are no listed patents left to litigate in phase-two. Pet'r Br. at 7. This unlikely hypothetical does not justify disregarding the plain meaning of §(*l*)(8). Sandoz overlooks that a patent may be newly issued or exclusively licensed to the sponsor ***after*** the sponsor provides its initial patent list under §(*l*)(3)(A). The BPCIA anticipates this, authorizing the sponsor to include such patents in phase-two litigation so long as it notifies the applicant of them "no later than 30 days after such issuance or licensing." §262(*l*)(8). Thus, even if there were no originally-listed patents remaining to be litigated in phase-two, the 180-day notice still serves an important purpose, giving the sponsor a fair opportunity to investigate the relevance

of later-issued or licensed patents, to decide whether to offer the applicant a license to them, or, if necessary, to seek preliminary injunctive relief based on infringement of any or all such patents.

If Sandoz believes there should be an exception to the required 180-day notice if there are no patents left to litigate in phase-two the answer is not to fault the statute for failing to cover every eventuality, however improbable. Instead, Sandoz should address its argument to Congress and seek amendment of the statute to address its hypothetical concern.

B. The FDA Must Approve the Biosimilar Product Before the Applicant Can Give its Notice of Commercial Marketing.

Subsection (*l*)(8) requires notice of commercial marketing "not later than 180 days before the date of the first commercial marketing of the biological product ***licensed under subsection (k)***." 42 U.S.C. §262(*l*)(8)(A) (emphasis added). The Federal Circuit correctly held that licensure of the biosimilar product was a necessary predicate for the notice of commercial marketing. The court reasoned that if Congress had intended to allow the notice to be sent prior to FDA approval, it would have used the phrase "the biological product that is the subject of" the subsection (k) application to refer to the future marketing of a biosimilar product, as it did in other provisions of the BPCIA. Pet. App. 20a; *see* 42 U.S.C. §262(*l*)(3)(B)(ii)(I), (*l*)(3)(C).

As the lower court explained, "[r]equiring that a product be licensed before notice of commercial

marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." Pet. App. 21a. Until FDA approval of the biosimilar application, the product, its uses (including indications, dosing and route of administration), and the processes by which it is manufactured are subject to change. Without a final product, the sponsor cannot make a fully informed decision about which patents are relevant to a request for preliminary injunctive relief. For this reason, the Federal Trade Commission, in its June 2009 report on biosimilars legislation, recommended against including any pre-approval patent resolution process: "the [applicant's] application and product may also change during the approval process, such that early patent litigation would no longer apply to the approved product. The litigation would be about a 'moving target.'" Fed. Trade Comm'n, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* 55.

If phase-two litigation proceeds before FDA approval, the suit could be premature or even unnecessary. Because the biosimilar launch date could not yet be predicted, a sponsor may be unable to demonstrate an imminent risk of irreparable harm and would have to guess when to seek a preliminary injunction. And if the product, its indications, or its method of manufacture remain subject to change, the sponsor may be unable to demonstrate substantial likelihood of proving infringement.

Sandoz's proposed interpretation of §(*l*)8(B) would undermine the entire two-phase structure of the BPCIA's patent scheme. If FDA approval is not required to permit the sending of a notice of

commercial marketing, what is? Under §(*l*)(8)(A), the required notice must be sent "at least" 180 days before launch. But how long before then can it be sent? Nowhere in Sandoz's brief does Sandoz propose a plausible earlier date for sending the notice and starting phase-two litigation, if not the date of FDA approval. Under Sandoz's theory, an applicant apparently could send notice any time after the FDA accepts the biosimilar application for review. In this case, Sandoz sent a notice of commercial marketing to Amgen ***the day after*** it received notice from the FDA accepting Sandoz's application for review. Pet. App. 8a. Sandoz's purported notice, stating only that marketing would begin after FDA approval, was way too early to be effective notice within the plain meaning and intent of §(*l*)(8).[11]

Plainly, the BPCIA's two-phase structure did not contemplate that the second phase of litigation could begin at (or before) the first phase. But under Sandoz's logic, if notice can be given as soon as the FDA accepts the application for review, then the sponsor would have the right to seek preliminary injunctive relief even before it files its complaint in phase-one litigation. If that were true, there would be no reason for the parties to negotiate the scope of phase-one—nor any reason for a two-phase litigation procedure at all. Instead, all patents that could reasonably be asserted against the as-yet unapproved

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[11] Sandoz appeared to recognize that its first purported notice was premature and ineffective: it gave another notice of commercial marketing to Amgen on the day that the FDA approved Sandoz's product. Pet. App. 8a-9a.

biosimilar product could become the subject of patent litigation as soon as the FDA accepts the biosimilar application for review and the applicant sends a Sandoz-like notice.

Not only would this strained interpretation of the BPCIA eviscerate phase-one under §(*l*)(6), it would undo the entire patent resolution scheme crafted by Congress. The result would be essentially random and unpredictable notices of commercial marketing followed by hurried motions for preliminary injunctions, fomenting litigation chaos and greatly burdening the district courts.

Contrary to the objections of Sandoz and its amici, this Court's holding that the 180-day notice of commercial marketing provision must follow after FDA approval would not necessarily extend the data exclusivity period for all reference products. Br. at 33. As a preliminary matter, for reference products approved more than 12 years ago, the concept of an "extension" is a misnomer, because these products were developed, approved and marketed with no expectation that biosimilar manufacturers could ever rely on the FDA's approval of the sponsor's product to support later approval of a competing product. Here, the 180-day notice "extends" nothing; it merely creates a modest six-month window for patent-dispute-resolution at the most logical time point,

between FDA approval of the biosimilar and its launch.[12]

As for more recently approved reference products, the FDA has yet to address the express distinction the BPCIA draws between "approval" and "effective approval": §(k)(7)(A) states that "*approval*" of a biosimilar application may not be "*made effective*" until 12 years after the reference product was first licensed under a BLA. Logically, then, "approval" can precede "effective approval."

Nothing in the BPCIA precludes the possibility that the FDA could grant approval, allowing an applicant to send its 180-day notice, before expiration of the 12-year period, such that biosimilar launch could occur promptly at the 12-year mark when the approval becomes effective. The statute confers broad authority on the FDA to issue guidances and regulations regarding licensure of a biological product under subsection (k). *See* 42 U.S.C. §262(k)(8). FDA approval prior to the 12-year mark would be akin to "tentative approval" under Hatch-Waxman. *See* 21 U.S.C. §355(j)(5)(B)(iv)(II)(dd). In a case decided after this one, the Federal Circuit suggested this approach:

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[12] Moreover, any alleged six-month "delay" in Sandoz's ability to commercialize its filgrastim product is the consequence of when Sandoz chose to file its abbreviated application. Sandoz waited to file until May 2014, more than four years after Congress created the subsection (k) pathway and long after the 12-year exclusivity period had expired for Amgen's reference product Neupogen®. Pet. App. 8a.

the FDA could "issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1062 (Fed. Cir. 2016).

Biosimilar applicants have complete control over when they file their applications. If an applicant submits its application to the FDA sufficiently in advance of the expiration of the reference product's 12-year exclusivity period and any patent disputes are resolved, it will have a chance to launch immediately upon the expiration of the 12-year period, when the FDA's approval becomes effective. The BPCIA's detailed patent-dispute-resolution provisions evidence Congress's intent to encourage early (rather than late) submission of biosimilar applications, so that patent issues would be resolved prior to market launch.

If, on the other hand, a biosimilar applicant submits its application near the end of the 12-year period, refuses to cooperate in the information-exchange process or engages in other calculated behavior to launch its product at risk, that applicant might be unable to launch at the 12-year mark. Such delay would be of the applicant's own making; nothing in the BPCIA guarantees that a biosimilar product can launch on the 12-year date irrespective of whether the applicant filed timely regulatory submissions or complied with the patent-dispute-resolution provisions.

In sum, the timing issue raised by Sandoz is a red herring, an artifact of the transitional period where some reference products, including Amgen's

Neupogen®, are already past their 12-year data-exclusivity period. The BPCIA was drafted with a focus on new and future products. It ought not be construed to solve a short-term inconvenience to Sandoz, but rather so that it works for decades to come. Over time, the six-month "delay" in market entry that biosimilar filgrastim faced will become increasingly rare, as the Federal Circuit recognized in *Amgen v. Apotex*:

> [I]t is implicit in the Biologics Act that any such delay beyond 12 years should occur less and less as time goes by. Doubtless, there will be some exclusivity period beyond 12 years in the early years of the Biologics Act, as biosimilars are introduced for reference products licensed well before the Act was adopted in 2010. But as time passes, more and more reference products will be newer, and a biosimilar-product applicant, entitled to file an application a mere four years after licensure of the reference product, § 262(k)(7)(B), can seek approval long before the 12-year exclusivity period is up.

Apotex, 827 F.3d at 1061-62. The increasingly rare fact pattern in this case cannot justify adopting a tortuous interpretation of §(*l*)(8). The plain meaning of the text requires a biosimilar applicant to give notice of commercial marketing after FDA approval of its product and at least 180 days prior to launch.

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment that 42 U.S.C. §262(*l*)(2)(A) is permissive, and affirm the judgment that 42 U.S.C. §262(*l*)(8)(A) is mandatory and can be sent only after the FDA approves the biosimilar product.

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RECORD AND BRIEFS

Nos. 15-1039, 15-1195

Supreme Court, U.S.
FILED
FEB 17 2017
OFFICE OF THE CLERK

In The
Supreme Court of the United States

SANDOZ, INC.,

Petitioner,

v.

AMGEN, INC. and
AMGEN MANUFACTURING LIMITED,

Respondents.

AMGEN, INC. and
AMGEN MANUFACTURING LIMITED,

Petitioners,

v.

SANDOZ, INC.,

Respondent.

On Writs Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF AMICUS CURIAE COHERUS BIOSCIENCES, INC. IN SUPPORT OF PETITIONER SANDOZ, INC.

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INTEREST OF *AMICUS CURIAE*[*]

Coherus Biosciences, Inc. is a leading developer of high-quality biosimilar therapeutics. Biologic drugs, such as antibodies and growth factors, are far more complex than traditional small molecule drugs. Biologics have transformed the treatment of cancer and autoimmune diseases but have also driven up health care costs, because of their high price. Expediting approval of biosimilar drugs dramatically cuts these costs, even after accounting for the fact that biosimilars are themselves expensive to develop and often require their own clinical trials, unlike traditional "generic" versions of small molecule drugs. Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) to provide a pathway for biosimilar approval while ensuring that any related patent disputes can be resolved in an orderly, efficient manner.

Coherus has a strong interest in the proper interpretation of the two provisions of the BPCIA at issue here. The FDA has accepted Coherus's subsection (k) application for a biosimilar of Neulasta®, a drug that protects cancer patients from infection after their chemotherapy treatments. Coherus also has two other promising biosimilars in Phase 3 clinical trials, on which it intends to file subsection (k) applications. Coherus will be using the BPCIA's procedures regularly and wants to ensure they are interpreted consistently with Congress's objectives of expediting biosimilar availability and reducing costs to the public and to federal programs such as Medicare and Medicaid.

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[*] No counsel for a party authored any part of this brief or made a monetary contribution to fund its preparation or submission. No one but *amicus* paid for its preparation or submission. All parties consent to the filing of this brief.

SUMMARY OF THE ARGUMENT

1. The Federal Circuit erred by adding a new 180-day exclusivity for branded biologics without any statutory basis. The BPCIA sensibly requires subsection (k) applicants who engage in the Act's patent exchanges to give notice of commercial marketing "not later than 180 days before" the first commercial marketing of the biosimilar product, to ensure that the reference product sponsor has sufficient time to seek an injunction on any patents excluded from the parties' "first-wave" patent litigation. The Federal Circuit converted this to a requirement that a subsection (k) applicant can only give the notice after it obtains FDA approval, which means that the branded drug gets an additional 180 days of market exclusivity where, as here, the 12-year market exclusivity the statute expressly provides has expired. This result, if allowed to stand, will significantly diminish the cost savings that Congress intended the BPCIA to achieve. And it is not necessary to wait until approval, as the Federal Circuit thought, in order to have a "crystallized" patent dispute. Other statutory provisions show that Congress determined the dispute was sufficiently crystallized upon the FDA's acceptance of a biosimilar application, without waiting for approval.

2. The Federal Circuit correctly held that subsection (k) applicants can opt not to disclose their application to the reference product sponsor. That determination is consistent with the statute, preserves maximum flexibility for all parties while protecting patent rights, and expedites availability of biosimilar drugs that are expected to get quick FDA approval.

ARGUMENT

I. The BPCIA Does Not Require a Subsection (k) Applicant to Disclose Its Application to the Reference Product Sponsor.

A. The Statutory Text Neither Requires Disclosure Nor Provides a Private Right of Action to Compel It.

1. The Federal Circuit correctly determined that the BPCIA does not require the party submitting an application for regulatory approval under 42 U.S.C. § 262(k) (a "subsection (k) applicant") to disclose its abbreviated Biologics License Application (aBLA) to the holder of the reference product license (the "reference product sponsor"). Although the Act states that the subsection (k) applicant "shall provide" its application, 42 U.S.C. § 262(l)(2)(A), the word "shall" has different meanings depending on its context. *See, e.g., Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 432 n.9 (1995) ("Though 'shall' generally means 'must,' legal writers sometimes use, or misuse, 'shall' to mean 'should,' 'will,' or even 'may.'"); David Mellinkoff, MELLINKOFF'S DICTIONARY OF AMERICAN LEGAL USAGE 402–403 (1992) ("shall" and "may" are "frequently treated as synonyms" and their meaning depends on context); Bryan A. Garner, GARNER'S DICTIONARY OF MODERN LEGAL USAGE 939 (2d ed. 1995) ("[C]ourts in virtually every English-speaking jurisdiction have held—by necessity—that shall means may in some contexts, and vice versa.").

Here, the statutory context shows that "shall" means "may," because it identifies a consequence when the subsection (k) applicant does not disclose its application—the reference product sponsor can immediately sue for infringement of "any patent that claims

the biological product or a use of the biological product." *See* 42 U.S.C. § 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). The statute's express inclusion of these remedies shows that Congress contemplated that a subsection (k) applicant might chose to not disclose its aBLA. If Congress had not contemplated this possibility, there would have been no need set out express remedies for non-disclosure.

2. The statute's remedy for non-disclosure—*i.e.*, an immediate right to sue for infringement—also leaves no room for an implicit private right of action to compel disclosure. "[E]xpress provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." *Alexander v. Sandoval*, 532 U.S. 275, 290 (2001). This Court therefore has refused to infer private rights of action that appeal to a court's equitable powers when Congress explicitly provides a different remedy. *See, e.g., Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378, 1385 (2015) (no private right of action to enforce provision of the Medicaid Act requiring states to act in a certain way where the statutory remedy was for the federal government to withhold funds for violations); *Alexander*, 532 U.S. at 290 (same for a provision of Title VI of the Civil Rights Act); *Stoneridge Inv. Partners v. Scientific-Atlanta*, 552 U.S. 148, 162-63 (2008) (refusing to infer private cause of action against alleged aiders and abettors of securities fraud where the statute for an action by the SEC against them). The same rationale applies here and forecloses judicial creation of a private right for anyone to compel disclosure of a subsection (k) applicant's aBLA.

Creating a private right of action would also create new ambiguities about the statutory procedure.

Assuming a reference product sponsor could file an action compelling disclosure of the biosimilar's application, and a court ordered the disclosure, what would happen next? Would the parties then be required to engage in the patent exchanges, negotiations, and first-wave litigation in § 262(l)(3)-(6), even though the reference product sponsor already has the right to sue for patent infringement? If so, what would happen to the reference product sponsor's ability to file an immediate infringement suit under § 262(l)(9)(c) once a court compelled disclosure? Would that remedy disappear, once the application had been disclosed? And, if not, how would it make sense both to have that remedy remain intact, and also to have the parties engage in the § 262(l)(3)-(6) negotiations and litigation? The statute does not address any of these questions, because it did not contemplate a private right of action. None have easy answers, and all would be avoided by declining to infer a right of action that Congress never provided.

Moreover, it is unnecessary to infer such a cause of action. As noted, the reference product sponsor can file an infringement suit immediately on any patent it is concerned the subsection (k) applicant may infringe. *See* 42 U.S.C. § 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii); *Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359 (Fed. Cir. 2000) (holding the patentee has a Rule 11 basis to sue where information about a defendant's product is not publicly available and it declines to provide it). Once the patent infringement litigation begins, the reference product sponsor can obtain the subsection (k) applicant's aBLA through document requests under Federal Rule of Civil Procedure 34. That is exactly what happened here. (Pet. App. 10a.) So there is no need to create a

new cause of action that will result in satellite litigation over disclosure when those issues will be resolved in the litigation that the statute expressly permits.

B. The Statute Protects All Parties' Rights and Preserves Flexibility by Making Disclosure Optional.

The statutory scheme of optional disclosure protects both parties' rights and allows flexibility for dealing with patent disputes, while still preserving an important role for the statutory exchanges.

1. The statute, appropriately, allows subsection (k) applicants to choose the most efficient path in the particular circumstances. For example, a subsection (k) applicant who believes it will obtain swift FDA approval, and who knows that there are no legitimate patent issues blocking approval, may conclude that withholding its application will expedite its path to market. The Act's patent exchanges take a significant amount of time—up to 230 days before a suit is filed. *See* 42 U.S.C. § 262(l)(3)-(6). Such an applicant may prefer to withhold its application, which would clear the way for immediate litigation and launch upon FDA approval, assuming, as discussed below, that the Federal Circuit's erroneous grant of an extra 180-day exclusivity is corrected. This case closely tracks that scenario—241 days elapsed between the FDA accepting Sandoz's application and approving its product. (Pet. App. 8a-9a.) If Sandoz had engaged in the statutory disclosures, it would have faced more hurdles to launching its product immediately upon approval. A patent infringement suit would have only just been filed on day 230, with little chance for a district court to analyze whether a preliminary injunction should issue by day 241. The court might be inclined (at least initially) to issue the injunction to avoid irreparable

harm to the reference product sponsor, even if the patent claims were exceedingly weak. In that situation, both the parties and the court would benefit by allowing the reference product sponsor to sue immediately, so that the district court had significant time to consider whether to issue an injunction before FDA approval.

2. The statute's optional disclosure procedure still fully protects the reference product sponsor's interest in enforcing any valid and infringed patents. As noted above, the patentee can immediately sue on "any patent that claims the biological product or a use of the biological product." *See* 42 U.S.C. § 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Moreover, the statute protects the reference product sponsor from any declaratory judgment action by the subsection (k) applicant who does not disclose its application or otherwise fails to participate in the patent exchanges. *See* 42 U.S.C. § 262(l)(9)(B), (C).

Judge Newman expressed concern that these provisions would still leave the reference product sponsor without a remedy for patents covering a method of manufacturing the biologic, (Pet. App. 37a-38a), but that is incorrect. As the Federal Circuit majority pointed out, 35 U.S.C. § 271(e)(2)(C)(ii), broadly provides for an infringement action against a non-disclosing subsection (k) applicant on any patent that could have been identified during the patent exchange, which included patents of manufacturing processes. (Pet. App. 16a n.3; *Hoffman-La Roche*, 213 F.3d at 1363-65.) There is thus no situation in which a subsection (k) applicant's decision not to disclose its aBLA can impose irreparable harm on a reference product sponsor whose patent is valid and infringed.

3. Although disclosure of the application is optional, this does not render this subsection of the BPCIA irrelevant. Subsection (k) applicants still have strong incentives to disclose in appropriate circumstances. Disclosing the application under § 262(l)(2)(A) triggers a series of exchanges that allow the subsection (k) applicant to determine which patents the reference product sponsor may actually assert in litigation, and to scrutinize the basis for such an assertion. *See* 42 U.S.C. § 262(l)(3). This process could significantly narrow the parties' dispute. One example is where the reference product sponsor has patents on multiple uses of a drug, yet the subsection (k) applicant is seeking approval for only one use. The information exchange should result in patents on other uses being removed from contention. Another example of disclosure of the aBLA and the subsequent information exchange simplifying the issue for litigation is where the subsection (k) applicant has plainly designed around patents claiming a particular formulation—the patents that do not claim the subsection (k) applicant's formulation should be removed from contention. In fact, a subsection (k) applicant can notify the reference product sponsor that it will not launch its biosimilar product before the expiration of a particular patent, again taking that patent entirely out of contention. Subsection (k) applicants will prefer to use the disclosure and negotiation process to eliminate these patents up front, rather than risking an immediate suit on those patents by refusing to disclose their application.

In addition, disclosing their aBLA allows the subsection (k) applicant to control the scope and timing of the initial patent litigation. Some reference product sponsors have sought to protect their blockbuster biologics with patent thickets of enormous complexity.

See, e.g., Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. Times (July 15, 2016), *available at* http://nyti.ms/2kUxW18 ("AbbVie, the company behind Humira, has amassed more than 70 newer patents, mostly in the last three years, covering formulations of the drug, manufacturing methods and use for specific diseases."). A subsection (k) applicant can use the statutory exchanges to identify a few key patents in the thicket and litigate those first, knowing that, if it wins, the rest may swiftly fall because they present common issues, while, if it loses, it will avoid significant unnecessary litigation costs on the rest of the thicket.

There is no reason to worry that interpreting the statute as written—*i.e.*, not to compel disclosure of the application or the ensuing exchanges—will unduly deter subsection (k) applicants from using the statutory exchange process when it is the most efficient path forward.

II. The Federal Circuit Erroneously Added 180 Days of Exclusivity Not Provided in the Act.

A. The BPCIA Does Not Require Any Notice of Commercial Marketing Where, as Here, there is No Information Exchange.

The Federal Circuit first erred by holding that the statute required notice of commercial marketing at all in this case. The BPCIA includes the notice of commercial marketing as a safety-valve for parties that engage in the information and patent exchange process in § 262(l)(2)-(4). That process culminates in a first wave of patent infringement litigation where the reference product sponsor believes it has valid patents that cover the biosimilar. *See* 42 U.S.C. § 262(l)(6).

That litigation might include only a subset of the patents that the reference sponsor has identified as potentially infringed by the subsection (k) applicant, and a declaratory judgment action by either party on the remaining patents is expressly precluded until notice of commercial marketing is given. *See* 42 U.S.C. §§ 262(l)(4)-(5) and (9)(A). Congress wanted to ensure that this procedure did not prevent a reference product sponsor from asserting a patent before a subsection (k) applicant actually starting selling its product. It provided that the subsection (k) applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(l)(8)(A). The BPCIA then further provides that, once notice is received, the reference sponsor "may seek a preliminary injunction" on any patent that was included in the parties' initial patent lists but not actually selected for the first-wave litigation. 42 U.S.C. § 262(l)(8)(B).

That makes sense when the parties have engaged in the BPCIA's information and patent exchanges. But where, as here, the subsection (k) applicant chooses not to disclose its application, the notice of commercial marketing serves no purpose. In that situation, other provisions already give the reference product sponsor the ability to seek such relief at any time. See 42 U.S.C. § 262(l)(9)(B), (C); 35 U.S.C. § 271(e)(2)(C)(ii). Therefore, as Judge Chen observed, "[g]iven the purpose of (l)(8) and its express assumption that the parties have already performed the steps in (l)(3) and (l)(4)-(l)(5), the most logical conclusion when reading (l)(8) in context is that (l)(8)'s vitality is predicated on the performance of the preceding steps in subsection (l)'s litigation management process." (Pet. App. 49a.) The Federal Circuit thus had no basis

to impose an additional 180-day exclusivity based on the timing of a notice of commercial marketing that Sandoz shouldn't have had to give in the first place.

B. Subsection (k) Applicants Can Give the Notice of Commercial Marketing Before Receiving FDA Approval.

Even assuming the statute requires a notice of commercial marketing here, the Federal Circuit erred in holding that 42 U.S.C. § 262(l)(8) prohibits the subsection (k) applicant from giving that notice until after it receives FDA licensure (approval). Section 262(l)(8) places only one restriction on the notice's timing: the "applicant shall provide notice to the reference product sponsor *not later than* 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." The text states only that the notice must be given by a certain date; it imposes no prohibition on giving it sooner. That should be the end of the inquiry.

The Federal Circuit suggested that the statute's reference to a "biological product licensed under subsection (k)" imposes some further timing restriction. (Pet. App. 20a-26a.) But § 262(l)(8) refers to a "licensed" product because it is describing the state of the product at the time it is marketed—a product cannot be marketed unless "a biologics license" is "in effect" for it. *See* 42 U.S.C. § 262(a)(1)(A). Nothing in the statute ties the notice date to the date of licensure. In fact, this paragraph of the statute refers to the "applicant" giving notice, which suggests it is permitted to give the notice before FDA approval—that is, while the company is still merely an "applicant," and not yet a licensee.

2. The Federal Circuit's erroneous statutory interpretation also contravenes the statutory purpose. The BPCIA was meant to expedite the entry of biosimilars after the 12-year market exclusivity period, unless the biosimilar infringes a valid patent. *See, e.g.*, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804. Yet the Federal Circuit's decision automatically adds an extra 180 days of market exclusivity in every case where the statute's exclusivity period has already expired. That is true regardless of whether the reference product sponsor could actually meet the requirements—*e.g.*, likelihood of success on the merits of a patent infringement claim—that are otherwise needed to obtain an injunction. (Pet. App. 23a-26a (ordering issuance of injunction against Sandoz without regard to whether Amgen was likely to prevail on a patent infringement claim).) Worse yet, the extra exclusivity period applies even when there are no patents at all that can reasonably be asserted, and thus no possibility of an injunction on the merits of a patent infringement claim (the express intention of the 180 day notice provision). This interpretation does not further the public interest that Congress intended to serve with the BPCIA.

The Federal Circuit's interpretation also contradicts other statutory provisions. The statute requires the notice (and ensuing 180 day window) so that the reference product sponsor "*may seek* a preliminary injunction." 42 U.S.C. § 262(l)(8)(B). But preliminary injunctions don't issue automatically—the patentee must show "a likelihood of success on the merits," among other factors. *Munaf v. Geren*, 553 U.S. 674, 690 (2008). Under the Federal Circuit's rule, however, an automatic injunction will be in effect for 180 days regardless of whether the traditional equitable criteria for issuing such an injunction are met. That is not

permissible. *See, e.g., eBay Inc. v. Mercexchange, L.L.C.*, 547 U.S. 388, 394 (2006) (halting the Federal Circuit's practice of automatically granting permanent injunctions and holding that "traditional principles of equity" govern the issuance of injunctions in patent cases).

The statute's 180-day period is meant to give the reference product sponsor adequate time to seek an injunction, not itself serve as an injunction. Indeed, if Congress had intended for a further, automatic 180-day delay, it would have provided for that expressly, just as it provided for an automatic 30-month stay in Hatch-Waxman litigation for small molecule generics on top of the 5-year statutory exclusivity period for new drug applications. *See* 21 U.S.C. §§ 355(j)(5)(B)(iii), 355(j)(5)(E)(ii), 355(j)(5)(F)(ii). The absence of such statutory language here shows that Congress did not want the extra 180-day stay the Federal Circuit imposed. It also shows that, as with the patent exchanges discussed earlier, Congress certainly did not create a private right of action that allows such an injunction. *See, e.g., Alexander*, 532 U.S. at 290; *Armstrong*, 135 S. Ct. at 1385; *Stoneridge*, 552 U.S. at 162-63.

C. The Federal Circuit Miscalculated the Consequences of its Extra Exclusivity.

1. The Federal Circuit downplayed the scope of the problem it had created, stating that the "extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." (Pet. App. 22a.) That assumption is incorrect, even leaving aside that Congress intended the BPCIA to benefit patients today, not just in the distant future. Today, many biosimilar applications

are pending for blockbuster biologics where the statutory market exclusivity has already expired, as the examples in the following table indicate:

Reference Drug	12-Year Exclusivity Expiration	2016 Annual Sales
Humira®	12/31/2014	$16 billion
Rituxan®	11/26/2009	$7.3 billion
Enbrel®	11/2/2010	$5.96 billion
Herceptin®	9/25/2010	$6.78 billion
Remicade®	8/24/2010	$1.62 billion
Epogen®	6/1/2001	$1.28 billion
Neulasta®	1/31/2014	$1.11 billion
Procrit®	6/1/2001	$1.06 billion
Neupogen®	2/20/2003	$765 million

See, e.g., http://bit.ly/2kBXUIh (Humira®); http://bit.ly/2kYz2LL (Enbrel®, Neulasta®, Epogen®, and Neupogen®); http://bit.ly/2ltfgZA (Procrit®, Remicade®); http://bit.ly/2keOAGV (Herceptin®, Rituxan®). Applications on biosimilars of many more such drugs will likely be filed, now that the Act provides a pathway to approval.

The Federal Circuit's extra 180-day market exclusivity will impose significant costs on consumers, insurers, and the federal government. Biologics cost, on average, over 20 times what a small molecule drug costs, with some therapies running to $200,000 a year. *See, e.g.*, LEIGH PURVIS, AARP PUBLIC POLICY INSTITUTE, A SENSE OF DÉJÀ VU: THE DEBATE SURROUNDING STATE BIOSIMILAR SUBSTITUTION LAWS 1 (2014),

available at http://bit.ly/2lyAG3i. A quintessential example is Humira®, whose annual cost per patient is $51,000 and whose 2016 annual sales were $16 billion, yet whose 12-year exclusivity ended over 2 years ago. *See* Judith A. Johnson, Cong. Research Serv., RL34045, FDA Regulation of Follow-On Biologics 1 (2010). Allowing 180 days of undeserved exclusivity for such a drug would waste billions of dollars. The cumulative impact of additional exclusivity is staggering when considered for all biologics, and it will only get worse as prices increase over time: "U.S. spending on biologics totaled $92 billion in 2013 (roughly 28 percent of all U.S. drug spending. This represented a nearly 10 percent increase over 2012 biologics spending." *See* ALEX BRILL, MATRIX ADVISORS, CONSIDERATIONS OF THE FDA'S IMPACT ON COMPETITION IN THE DRUG INDUSTRY 6 (Nov. 2014), *available at* http://bit.ly/2kvxjKq. The Federal Trade Commission reports that these increased costs will hurt everyone, not just patients on the biologics, because they "will cause the cost of health insurance to rise for all insureds, not just those using biologic products." *See* Comment of the Staff of the Federal Trade Commission, 80 Fed. Reg. 52296 (Aug. 28, 2015), *available at* http://bit.ly/1P0OJe4.

2. The Federal Circuit's other basis for preventing subsection (k) applicants from providing notice of commercial marketing until FDA approval—*i.e.*, that this will "ensure[] the existence of a fully crystallized dispute regarding the need for injunctive relief"—is equally erroneous. The reference product sponsor and the subsection (k) applicant will already have a concrete dispute upon the FDA's acceptance of the aBLA. The statute provides that the acceptance of such an application creates a concrete dispute that can, in all

cases, serve as the basis for a claim of patent infringement. *See* 42 U.S.C. §§ 262(l)(6), 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C). A patentee can ask for a preliminary injunction in such litigation, just as could any plaintiff. Given that Congress thought that there was a sufficiently concrete controversy to provide for "first-wave" litigation upon the FDA's acceptance of the subsection (k) applicant's application, there is no reason to think that, in writing § 262(l)(8), it changed its mind and thought that the controversy on any other patents would not be sufficiently crystallized until after FDA approval.

It is true that biosimilars are complex products, that the application might be amended in response to the FDA's input, and that such amendments might impact the infringement analysis. But none of that is a reason to think that § 262(l)(8)'s required notice of commercial marketing is meant to delay litigation completely until after there is an approved product. Quite the contrary: the statute is designed to resolve some or all of the parties' patent disputes *before* the biosimilar application is approved, so that, if it turns out the proposed product will not infringe any valid patents, it can be launched—and the public can enjoy the befits that come with it—immediately upon expiration of the 12 year exclusivity. Section 262(l)(8) simply provides a safety valve that permits a reference sponsor who has engaged in the statutory patent identifications to immediately sue on any patent that the parties initially include on their lists of potential implicated patents under § 262(l)(3), yet do not include in the first-wave of litigation. After such a suit begins, the reference sponsor can propound discovery requests under Federal Rules of Civil Procedure 33 and 34 to monitor amendments to the biosimilar application, and, should such an amendment impact the

infringement analysis, it can add or remove patents from the case as appropriate, something that is routinely done in cases involving generic drugs under the Hatch-Waxman Act.

3. The Federal Circuit's added exclusivity imposed particularly unfortunate consequences this case. Sandoz's initial notice of commercial marketing (provided in July 8, 2014 at the same time the FDA accepted its application) was given 241 days before the FDA approved its product on March 6, 2015. That is a couple months more than the 180-day minimum notice that the statute would have required for Sandoz to launch on its approval date. Sandoz's initial July 8, 2014 notice also reasonably stated that it believed the application would be approved in "Q1/2 of 2015," which turned out to be true. (C.A. J.A.1472.) Had the Federal Circuit simply treated the initial notice as effective, then § 262(l)(8) would have worked precisely as it should have. Amgen would have had ample time to seek a preliminary injunction for patent infringement before launch (which it chose not to do), while Sandoz would have been able to launch its product immediately upon approval (since we know Amgen did not, in fact, seek a patent-based preliminary injunction), thus expediting cost-savings to patients, insurers, and the government, and preserving judicial resources. Instead, the public had to wait half a year after approval of Sandoz's biosimilar product to see the cost savings that the BPCIA was designed to deliver immediately.

It is not as if Sandoz provided its notice of commercial marketing in bad faith, knowing that approval was still years away. Indeed, subsection (k) applicants who engage in the information exchanges un-

der § 262(l)(2)-(4) have little incentive to give the notice before they actually believe launch is imminent. The benefit to the subsection (k) applicant of engaging in that information exchange is that it can control the pace and scope of litigation. But once the subsection (k) applicant gives notice under § 262(l)(8), it exposes itself to suit and preliminary injunction proceedings on *any* listed patent. So subsection (k) applicants won't give notice unless approval really is imminent. And the notice will not matter for subsection (k) applicants who do not engage in the § 262(l)(2)-(l)(4) information exchanges: they are immediately subject to suit on any patent anyway, regardless of whether or when they give notice. *See* 42 U.S.C. § 262(l)(9)(C). Either way, the reference product sponsor has ample time to assess the biosimilar prior to launch and seek enforcement of valid and infringed patents. As it stands now, the Federal Circuit's interpretation denies patients access to lower cost medicines and unnecessarily costs payors—including the U.S. government—billions of dollars. This Court should thus enforce the statute that Congress actually wrote and eliminate the Federal Circuit's extra 180-day exclusivity period.

CONCLUSION

For the reasons above, *amicus* encourages the Court to reverse the Federal Circuit's conclusion that 42 U.S.C. § 262(l)(8) requires that notice of commercial marketing be given only after FDA approval, creating a windfall extra 180 days of brand market exclusivity, and encourages the Court to affirm the Federal Circuit's holding that the subsection (k) applicant can opt not to disclose its aBLA under § 262(l)(2).

Respectfully submitted,

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AND
RIEFS

FILED
MAR 17 2013

Nos. 15-1039 and 15-1195

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC., ET AL.,

Respondents.

ON WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* GENENTECH, INC. IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

Genentech is one of the world's leading biotechnology companies. As such, it develops treatments for unmet medical needs, especially in the areas of oncology, immunology, neuroscience, metabolism, and infectious disease. Its products include some of the most groundbreaking treatments for cancer, heart attack and stroke, macular degeneration, and other serious or life-threatening medical conditions. To accomplish its critical public-health goals, Genentech invests heavily in research and development. Its approximately 1,200 researchers and scientists and 125 postdocs work in state-of-the-art facilities to push the boundaries of medical knowledge—including by developing biological drugs, or "biologics." Given this commitment to developing innovative treatments using biologics, Genentech has a significant interest in ensuring a proper interpretation of the Biologics Price Competition and Innovation Act of 2009 (the Biologics Act).[1]

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[1] The parties have consented to the filing of this *amicus* brief. No counsel for a party authored the brief in whole or in part. No party, counsel for a party, or any person other than *amicus* and its counsel made a monetary contribution intended to fund the preparation or submission of the brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Biologics Act is a litigation-focused statute. Like the Patent Act (which has governed litigation involving patentees for more than a century), and the Hatch-Waxman Act (which governs litigation over generic drugs), the Biologics Act regulates litigation over patent rights. As Sandoz itself recognizes, among the Act's goals is to "facilitat[e] early resolution of potential patent disputes" between biologic pioneers and subsequent producers of biosimilar products. Sandoz Br. 10. It does so by requiring that pioneers and biosimilar applicants exchange certain information, and by specifying the process for litigation that may (and ordinarily will) follow. *See id.* at 10-12.

Despite the fact that private litigation is at the heart of the Biologics Act, Sandoz contends that enforcing the 180-day notice provision contained in 42 U.S.C. § 262(*l*)(8)(A) amounts to impermissibly implying a private right of action. Sandoz Br. 28-29, 43-56 (citing, among other cases, *Alexander v. Sandoval*, 532 U.S. 275 (2001)).

That argument misunderstands this Court's jurisprudence concerning private rights of action. The implied-right-of-action cases on which Sandoz relies concern statutes in which enforcement occurs through mechanisms other than private lawsuits, such as actions by the government. Here, by contrast, Congress has enacted pages and pages of statutory text directed at structuring litigation between private parties. Sandoz's contrary argument distorts the

implied-right-of-action cases beyond recognition by reducing Congress's express notice requirement to a nullity. And it ignores the established principle that Congress does not implicitly abrogate the federal courts' inherent authority to award all appropriate relief for violations of federal law. Sandoz ends up proposing a statutory interpretation that is a recipe for chaos, requiring billion-dollar questions involving lifesaving drugs to be litigated in a hasty fashion. Neither the Biologics Act nor this Court's cases support that result.

1. The best way to understand the Biologics Act is to begin with what it does *not* do. The Act does not keep anyone out of the market for biologics. It does not prevent any company from undertaking the ordinary process—which every biologics pioneer goes through—of proving the safety and efficacy of its drugs to the FDA. If a company does so successfully, it can begin selling its products straightaway.

In addition, the Biologics Act provides a second route to market entry—a shortcut that offers streamlined FDA approvals. Specifically, a company may file an abbreviated licensing application, which allows it to piggyback on the earlier efforts of a biologic pioneer. The applicant need only show that its product is biosimilar to the pioneer biologic.

This shortcut is immensely valuable for biosimilar applicants, because it saves them the time and expense of a full FDA inquiry into safety and efficacy. But Congress understood that shortcuts can lead to wrong turns, so it made sure to include safeguards. It imposed a series of detailed

requirements on both the applicants seeking to take the shortcut and on the pioneers who initially proved the safety and efficacy of their biologics to the FDA. The reasons for these requirements are simple and salutary: to promote competition while fostering innovation; and to avoid the litigation free-for-all that otherwise would result.

Among the Act's key provisions is a mandatory notice requirement. After the FDA licenses a biosimilar product to an applicant seeking to use the statutory shortcut, the applicant must notify the biologic pioneer at least 180 days before it goes to market. This notice period gives the pioneer time to seek a preliminary injunction based on any patents that are not already the subject of litigation, pursuant to the multi-step process set forth in 42 U.S.C. § 262(*l*). *See* Pet. App. 6a-7a; *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1055-58 (Fed. Cir. 2016). And, if the pioneer does seek injunctive relief, the notice provision (and corresponding limitation on marketing the biosimilar drug) enables the reviewing court to assess the patent-law questions with appropriate deliberation—rather than being forced into a snap judgment with months' (and hundreds of millions of dollars') worth of the biosimilar product already on trucks, ready to roll. As Judge Taranto recently explained, this framework reflects Congress's "aim to avoid the uncertainties and deficiencies associated with a process in which requests for temporary restraining orders and preliminary injunctions are presented and adjudicated on short notice." *Apotex*, 827 F.3d at 1063.

2. Sandoz wants to take the statutory shortcut without paying the toll. It seeks to reap the benefits of the abbreviated licensing procedure while disregarding the accompanying requirements. The Court should prevent Sandoz—and the scores of biosimilar applicants who would mimic its approach—from ignoring Congress's explicit instructions. As Amgen explains, the Biologics Act makes clear that notice of commercial marketing must *follow* the FDA's issuance of a license. Amgen Br. 27-42. That argument about the clear text and structure of the Act need not be rehashed here. The same is true of Amgen's further explanation of how the Act requires—again through the use of clear, mandatory language—that a biosimilar applicant furnish its application and manufacturing information to the biologic pioneer. *Id.* at 58-67.

3. Rather than repeating those arguments, Genentech submits this brief to address Sandoz's claim that to enforce the Biologics Act's notice requirement is to imply a private right of action where none exists. *See* Sandoz Br. 43-44; *see also* U.S. Br. 35.

On the contrary, the Act—like the broader system of patent enforcement to which it belongs—revolves around disputes litigated between private parties. It is predicated upon the ability of biologic pioneers to protect their own rights. Sandoz acknowledges as much with its repeated references to private suits for patent infringement. *E.g.*, Sandoz Br. 5 ("[A]ll routes lead to only one place: patent litigation."). There is no need to "imply" or "create" rights of action. They are already there.

Sandoz's argument also is unmoored from the considerations and concerns that animate the Court's implied-right-of-action cases. Its brief relies on cases in which private lawsuits were excluded because Congress had created other mechanisms for enforcing its statutes. Here, however, Sandoz points to no other way to enforce the Biologics Act. This is not a situation in which Congress created a statutory scheme for an administrative agency to enforce. *See, e.g., Alexander*, 532 U.S. at 289. Nor is there any suggestion that criminal penalties attach to noncompliance. *See, e.g., Stoneridge Inv. Partners, LLC. v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 166 (2008). Accordingly, Sandoz is not simply arguing against *private* enforcement of the Act's notice requirement. It is arguing against *any* enforcement.

4. As a fallback, Sandoz contends that even if there is a private right to enforce the Act's notice requirement, courts are powerless to award equitable relief for violations. Sandoz Br. 43-45. But Sandoz's argument has matters backwards. Once it is established that a private right of action exists, the presumption is that judges may award any appropriate relief, including equitable relief. *See, e.g., Franklin v. Gwinnett Cty. Pub. Sch.*, 503 U.S. 60, 69 (1992). Only a clear indication from Congress can support the withdrawal of equitable powers from the federal courts. Sandoz points to no such indication at all.

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For Sandoz to be right, it has to show that (a) Congress inserted an explicit and unqualified

notice requirement in the Biologics Act but did not intend for any entity, public or private, to enforce it; (b) at the same time, Congress meant to sweep away the federal courts' inherent equitable powers to enforce the notice provision, despite not having said a word to that effect; and (c) despite the Act's obvious attempt to bring order and deliberation to litigation over biologics, Congress was actually content to force courts to make snap judgments about complex patent-infringement claims at the very moment biosimilar applicants stand ready to (or have already begun to) enter the market. It would be strange for Congress to have gone to the trouble of developing a careful statutory regime that was so easily circumvented. And, in fact, Congress did no such thing. The Biologics Act creates a system for ensuring that biosimilar drugs are brought onto the market in an orderly fashion. This Court should interpret the Act according to its plain text and evident purpose—both of which entail private enforcement of the notice requirement.

ARGUMENT

I. This Court's Cases Support A Private Right Of Action For Violations Of The Notice Requirement.

A. If private parties cannot enforce the notice requirement, no one can.

There's no dispute that the Biologics Act contains a notice provision. The only questions are when it must be satisfied and how it may be enforced. According to Sandoz, there is no private right of action that enables a pioneer—or, as we will see, anybody

else—to enforce Congress's clear directive. *See* Sandoz Br. 43-44; *see also* U.S. Br. 20-22. This argument relies upon the Court's cases concerning implied rights of action, and it fails under any reasonable understanding of those cases.

Before explaining why this is so, it's important to recognize that a threshold argument raised by Amgen pretermits any inquiry into implied rights of action in this case. As Amgen explains, even if the Biologics Act didn't itself allow for private enforcement, that would be no basis for ruling against Amgen here. Amgen Br. 42-43. That is because Amgen has asserted causes of action that unquestionably are available to a private litigant, including state-law claims for unfair competition and unlawful business practices. *See id.*; Pet. App. 9a. Unless those claims are preempted—and Sandoz hasn't argued (and indeed has waived any argument) that they are, *see* Amgen Br. 43—Sandoz's argument against implied rights of action gets it nowhere. *Cf. Apotex*, 827 F.3d at 1063 ("Apotex has not asserted that (8)(A) creates no privately enforceable right, even when asserted as part of an infringement action ....").

In addition, Sandoz's argument about implied rights of action fails even on its own terms.

1. As Sandoz's own brief makes clear, the Biologics Act bears no resemblance to any statute, or any situation, addressed by the Court's decisions on implied rights of action. While the Court has indeed cautioned against conjuring up private lawsuits that Congress did not authorize—as when a government agency or prosecutor is exclusively authorized to

enforce a federal statute—Sandoz seeks a dramatic extension of the doctrine. It asks the Court to displace private suits in a domain where private litigation is the familiar norm; where the statute explicitly contemplates extensive litigation between private parties; and despite the fact that private actions are the only way to enforce the federal law in question.

To understand the dramatic extension that Sandoz requests, it is helpful to review the trajectory of this Court's jurisprudence. During the middle of the twentieth century, the Court sometimes would imply the existence of a private right of action in a statute, in order to effectuate the statute's perceived goals, without conducting a detailed inquiry into Congress's views about the appropriate mechanism for enforcement. The "high water mark of judicially inferred remedies" may have been *J.I. Case Co. v. Borak*, 377 U.S. 426 (1964). *See* Richard H. Fallon, Jr. et al., *Hart & Wechsler's The Federal Courts and the Federal System* 739 (7th ed. 2015). There, the Court reasoned that courts must be "alert to provide such remedies as are necessary to make effective the congressional purpose" in enacting a statute. *Borak*, 377 U.S. at 433.

Whether *Borak* was merely an anomaly,[2] or

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[2] *See Cannon v. Univ. of Chicago*, 441 U.S. 677, 736 (1979) (Powell, J., dissenting) ("*Borak*, rather than signaling the start of a trend in this Court, constitutes a singular and ... aberrant interpretation of a federal regulatory statute.").

emblematic of a broader trend,[3] by the 1970s the Court had shifted its focus to more evident indications of congressional intent. *See Alexander*, 532 U.S. at 287 (noting that in *Cort v. Ash*, 422 U.S. 66 (1975), the Court "abandoned" the old "understanding" exemplified by *Borak*, "and ha[s] not returned to it since"). Thus, the Court has explained, the judicial role is to implement legislative choices about the proper means of enforcement. *See, e.g., Gonzaga Univ. v. Doe*, 536 U.S. 273, 285 (2002) (explaining that the relevant question is "whether or not Congress intended to confer individual rights upon a class of beneficiaries").

The Court accordingly "swor[e] off the habit of venturing beyond Congress's intent," instead treating the discernment of enforcement mechanisms as a question of statutory interpretation like any other. *Alexander*, 532 U.S. at 287. The key question is not how best to effectuate Congress's goals; it is how Congress itself intended enforcement to occur. *See, e.g., Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 15-16 (1979) ("[W]hat must ultimately be determined is whether Congress intended to create the private remedy asserted ...."). So in interpreting a statute's remedial scheme, the starting points for analysis are the same ones a court uses in interpreting the substantive rights protected by the statute: "text and structure." *Alexander*, 532 U.S. at 288.

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[3] *See Alexander*, 532 U.S. at 287 (describing *Borak* as emblematic of "the understanding of private causes of action that held sway" in the 1960s).

This approach is rooted in the separation of powers. The Court has taught that it is for "Congress rather than the courts" to "control[] the availability of remedies for violations of statutes." *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 508 n.9 (1990). Just as judges must respect legislative decisions about the substance of federal law, they must likewise respect legislative decisions about how rights are to be enforced. *See Alexander*, 532 U.S. at 286 ("Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress.").

2. These principles are particularly important when Congress has created mechanisms other than private lawsuits for enforcing the rights it created.

For instance, in one of Sandoz's primary cases, *Alexander v. Sandoval*, the Court rejected the suitability of private enforcement when the relevant statute was "'phrased as a directive *to federal agencies* engaged in the distribution of public funds.'" 532 U.S. at 289 (emphasis added) (quoting *Univs. Research Ass'n, Inc. v. Coutu*, 450 U.S. 754, 772 (1981)). After all, when Congress has given enforcement responsibility to an agency, "'[t]here [is] far less reason to infer a private remedy in favor of individual persons.'" *Id.* (quoting *Cannon*, 441 U.S. at 690-91).

Those same considerations applied in *Gonzaga*, upon which Sandoz also relies. Sandoz Br. 43-44. There, the Court declined to find a private right of action to enforce the Family Educational Rights and Privacy Act. *Gonzaga*, 536 U.S. at 276. In so doing, it again relied on an agency's enforcement authority: "Congress expressly authorized the Secretary of

Education to 'deal with violations' of the Act ... and required the Secretary to 'establish or designate [a] review board' for investigating and adjudicating such violations." *Id.* at 289 (emphasis omitted, second alteration in original) (quoting 20 U.S.C. § 1232g); *see also id.* at 290 (distinguishing cases in which "an aggrieved individual lacked any federal review mechanism").

So too in *Stoneridge*, cited in U.S. Br. 21, and *Touche Ross & Co. v. Redington*, 442 U.S. 560 (1979), cited in Sandoz Br. 51, 53, and U.S. Br. 20-21. Both cases declined to find private rights of action, and both relied on the fact that the underlying statutes were meant to be enforced by prosecutors or by financial regulators. In *Stoneridge*, the Court noted the availability of "criminal penalties ... and civil enforcement by the SEC" to enforce legal rights. 552 U.S. at 166. That federal authority was ample to enforce the statute; the SEC's "enforcement power is not toothless," and "criminal penalties are a strong deterrent." *Id.* And in *Touche Ross*, the Court implied no private right of action because it found that "[t]he information contained in the [reports required by the statute] is intended to provide the [SEC], the [New York Stock] Exchange, and other authorities with a sufficiently early warning to enable *them* to take appropriate action to protect investors." 442 U.S. at 570 (emphasis added).[4]

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[4] *See also, e.g., Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 117 (2011) (finding no private right of action where "Congress vested authority to oversee compliance with the" relevant law in the Department of Health and Human Services "and assigned no auxiliary enforcement role to covered entities"); *Horne*

This same principle explains the Federal Circuit decisions that Mylan relies upon in its amicus brief supporting Sandoz. *See* Mylan Br. 13-14. In those cases, the Federal Circuit held that certain procedural requirements of the Hatch-Waxman Act did not create a private right of action that could be enforced in private litigation.[5] But the result in those cases was driven by the fact that the Hatch-Waxman Act not only provides for government enforcement of its provisions—it requires it. The Federal Food, Drug, and Cosmetic Act, of which the Hatch-Waxman Act is a part, mandates that all "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Indeed, that mandate is so clear that the parties in *Mylan Pharms., Inc. v. Thompson* had

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v. Flores, 557 U.S. 433, 456 n.6 (2009) (finding that the No Child Left Behind Act "is enforceable only by the agency charged with administering it" rather than by private parties); *Karahalios v. Nat'l Fed'n of Fed. Emps., Local 1263*, 489 U.S. 527, 529 (1989) (finding no private right of action "[b]ecause we decide that Congress vested exclusive authority over [the relevant statutory] duty in the Federal Labor Relations Authority ... and its General Counsel").

[5] *See Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 783 (Fed. Cir. 2002) (holding no right to challenge generic company's paragraph IV certification in infringement litigation); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002) (holding district court in infringement action could not sanction allegedly improper conduct before FDA); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1329-30 (Fed. Cir. 2001) (holding no private enforcement of statutory limitations on which patents may be listed in "Orange Book"), *superseded by statute*, 21 U.S.C. § 355(j)(5)(C)(ii)(I), *as recognized in Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408-09 (2012).

to agree that a private action was barred. 268 F.3d 1323, 1330 (Fed. Cir. 2001).[6]

3. These cases exemplify situations in which Congress has charged a governmental authority with enforcing a statute. And in those circumstances, there is little reason to imply an additional right for private individuals absent some indication in the statute. At the same time, the cases leave undisturbed the commonsense proposition that it would be exceedingly odd for Congress to go to the trouble of enacting a statute unless *someone* was empowered to enforce it.

That latter situation is the one presented by the Biologics Act. Sandoz does not suggest that there is anyone other than private actors who is empowered to enforce the notice requirement. *Cf. Apotex*, 827 F.3d at 1064 (noting in a related case that the defendant did not "identif[y] any statutory commitment to a government agency of responsibility or authority to enforce or to seek to enforce the (8)(A) command"). When it comes to enforcing the 180-day notice requirement, the enforcer is a private actor, or

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[6] Notably, Congress subsequently overruled different aspects of this decision, in ways that support the rule we advocate here. Specifically, Congress provided that a generic applicant sued for patent infringement may bring a counterclaim to challenge the allegedly improper inclusion of a patent in the Orange Book. 21 U.S.C. § 355(j)(5)(C)(ii)(I); *see Caraco*, 566 U.S. at 408-09. In so doing, Congress took care to specify that that defense does not create an independent cause of action. It therefore reinforced that (unlike here) government enforcement remains paramount in the FDCA context, and that Congress knows how to specify government enforcement when it wishes to do so.

it is nobody. The prospect of private actions being displaced by other enforcement mechanisms, which is at the heart of the cases Sandoz cites, is simply absent. Instead, Sandoz finds itself forced to argue that for all its care and specificity, Congress intended that the notice requirement would be unenforceable. Not only is this inference implausible; it finds no support in this Court's right-of-action cases.

B. No right of action need be "implied" in this case, for the Biologics Act revolves around litigation between private parties.

As the previous section illustrated, the contrast between this case and the Court's implied-right decisions couldn't be starker. The Biologics Act is all about private litigation between private parties, and nowhere does it discuss or authorize governmental enforcement.

The notice provision falls within subsection *l* of the Act, titled "Patents," which spells out an intricate and thorough procedure for ensuring the orderly and informed litigation of patent rights. Upon filing for shortcut approval, the biosimilar applicant must disclose information about its application to the biologic pioneer so that the pioneer can assess whether its patent rights are threatened. 42 U.S.C. § 262(*l*)(2). Following this disclosure, the biologic pioneer and the biosimilar applicant exchange lists of patents that may be implicated by the application. *See id.* § 262(*l*)(3)(A), (B)(i). The applicant must then explain its basis for believing that there is no violation of patent rights—for example, because the asserted

patents are invalid, the biosimilar product will not infringe them, or the product will not be marketed until the patent expires. *See id.* § 262(*l*)(3)(B)(ii). The parties ultimately winnow the list of patents down to a set—the so-called "Round One" patents—to be litigated in an "Immediate Patent Infringement Action." *Id.* § 262(*l*)(4)-(6). In short, the statute is structured around private litigation.

The 180-day notice provision is part and parcel of this private-litigation-based regime. It authorizes actions by biologic pioneers to seek "a preliminary injunction prohibiting the [biosimilar applicant] from engaging in the commercial manufacture or sale" of biologics until patent rights that were *not* part of the Round One litigation are resolved. *Id.* § 262(*l*)(8)(B). In addition, Congress specified circumstances under which pioneers may bring declaratory judgments to enforce their rights. *Id.* § 262(*l*)(9). In short, in setting out these procedures, Congress confirmed what everyone already knew: In American law, the enforcement of patents falls to private actors bringing private lawsuits. Those suits are the ubiquitous and well-known mechanism for safeguarding "patent rights whose fair and unhurried adjudication" the notice requirement "is designed to protect." *Apotex*, 827 F.3d at 1063-64.

Sandoz does not dispute that patent-holders are entitled to protect their rights in court. As discussed above, neither does it argue that there is an administrative agency or law-enforcement body charged with enforcing the notice requirement. It argues, in effect, that no one may enforce the notice requirement—which is to say, that the requirement

isn't a requirement at all. Nothing in the Biologics Act's text, structure, or context supports such a reading.

C. An unenforceable notice requirement would have consequences that Congress cannot have intended.

The discussion thus far has explained why concerns about implied rights of action are misplaced in this case, and how private enforcement of the Biologics Act coheres with the Act's plain text as well as the broader system of American patent law. Those points are more than adequate to dispose of Sandoz's arguments for rendering the notice requirement unenforceable. But Sandoz's position also suffers from another flaw: It would yield a regime of litigation whose perverse consequences Congress could not possibly have intended. Sandoz's view of the Act would lead to hurried proceedings involving remarkably high stakes—in short, judges making billion-dollar judgments, sometimes in the course of a day's litigation.

A simple illustration shows why this is so. Imagine a biosimilar applicant who submits a shortcut application to the FDA and begins complying with the Act—for example, by sending the biologic pioneer a copy of its application and a description of its manufacturing process. 42 U.S.C. § 262(*l*)(2)(A). The applicant will appear to the world to be complying with the Act while it seeks FDA approval to market its product. Now imagine that the FDA issues a license, and the applicant immediately begins selling its product—without having given notice to the

pioneer. In short, the applicant decides to ignore the notice requirement Congress expressly set forth in § 262(*l*)(8)(A).

The ending of this story is utterly predictable. The moment the applicant has received FDA approval to market the biosimilar, it will ship as much product as possible, as fast as possible. (More on that in a moment.) And the biologic pioneer, in order to prevent the market from being flooded with a product whose legality hasn't been resolved, will seek expedited proceedings in an effort to restrain those sales. As Judge Taranto explained, without the possibility of a straightforward proceeding that merely considers whether the notice requirement (and accompanying marketing limitation) was violated, a biologic pioneer "will have to race to court for immediate relief to avoid irreparable harm from market entry." *Apotex*, 827 F.3d at 1065. Rather than making a simple motion to enforce the 180-day buffer Congress created, the pioneer will need to argue for "a temporary restraining order or a preliminary injunction" that involves the full panoply of patent issues. *Id.* In short, rather than resolving the motion with a quick glance at the calendar, the district court will need to conduct an intensive assessment of the parties' positions, including the likelihood that the pioneer will ultimately prevail on its claim of patent infringement. This is "precisely the hurried motion practice that [the notice requirement] is designed to replace by ensuring a defined amount of time for pre-launch litigation." *Id.*

Stranger still, Sandoz's position would apply in equal measure to an applicant who gives notice of its

intent to market beginning in 180 days, only to break its word and begin selling its product a day later. Again, the pioneer would need to race to court in the hope of convincing a judge to enter an immediate TRO in a high-stakes case involving complex technologies and complicated claims. *See id.* at 1062 (a biologic pioneer "needs time to make a decision about seeking relief based on yet-to-be litigated patents, and a district court needs time for litigants to prepare their cases, in a complicated area, to provide a reliable basis for judgment").[7]

This is the opposite of how the Biologics Act is supposed to work. The notice requirement, and the accompanying marketing limitation, are designed to bring order and predictability to litigation. It is "evident on the face of § 262(*l*)" and "confirm[ed]" by the "Act's legislative history" that Congress intended to "avoid the uncertainties and deficiencies associated with a process in which requests for temporary restraining orders and preliminary injunctions are

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[7] The same is true under the compromise proposed by the government. The Acting Solicitor General suggests that, when considering whether to issue a preliminary injunction pending the resolution of infringement claims, district courts may take into account an applicant's failure to give notice. U.S. Br. 36. But this is little solace, for district courts would still be put to the task of making snap judgments about the likelihood of success in patent disputes as biosimilars began rushing into the market notwithstanding unresolved claims of infringement. In fact, this proposed compromise may actually make matters worse. In addition to all of the other issues being litigated in expedited fashion, district courts would have to wade through an additional set of issues: whether notice was given, whether any failure to give notice was in bad faith, whether the failure prejudiced the biologic pioneer, and so forth.

presented and adjudicated on short notice." *Apotex*, 827 F.3d at 1063.

These are not fanciful or hypothetical concerns; they have plagued Hatch-Waxman litigation. In that related context, courts are often forced to decide at breakneck speed whether to delay generic drugs' entry into the market. An injunction that turns out to be unwarranted threatens to "thwart[] the statutory purpose of achieving swift competition by generics." *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1311 (D.C. Cir. 2010). Yet if the court delays before acting, it effectively gives the generic manufacturer "precisely the relief it seeks, simply in order to allow the court time to decide whether such relief was warranted." *Id.*

This has placed courts in an "awkward bind," to put things mildly. *See AstraZeneca Pharm. LP v. Burwell*, 197 F. Supp. 3d 53, 55-58 (D.D.C. 2016). In *AstraZeneca*, for example, the court and the patent holder reviewed the FDA's approval decision in less than an hour, then went straight into oral argument followed by an oral decision. Transcript of July 19, 2016, Hearing, Dkt. 77, at 7-8, 64, *AstraZeneca*, No. 1:16-cv-1336 (D.D.C. June 30, 2016). This lightning-fast, patched-together procedure was necessary because, as the generic drug producers themselves explained, "months worth of product" was "loaded onto trucks" and "sitting in quarantine at distributors[,] which is all common practice when generics launch their generic products." *Id.* at 54, 56. AstraZeneca, meanwhile, stood to suffer losses "in the neighborhood of $400,000,000" if those generics

entered the market, "and the company would have no avenue of suit to recover that amount." *Id.* at 73.

Likewise, in a dispute involving generic versions of the antipsychotic drug Abilify, a district court held a hearing on the patent holder's motion for a TRO or preliminary injunction "just two hours after" FDA approval. *Otsuka Pharm. Co. v. Burwell*, No. 8:2015-cv-852, 2015 WL 1962240, at *1 (D. Md. Apr. 29, 2015). The very next day, the court churned out a 24-page decision that required it to analyze the FDA's approval of the generics' labeling under the two-step *Chevron* framework. A deliberative process that customarily takes months was crammed into a day. *See also* Amgen Br. 41-42 (providing additional examples).

Congress plainly learned from this experience, which long predates the Biologics Act. It inserted a 180-day notice requirement in the Biologics Act to avoid rapid-fire litigation in situations where mistakes can never fully be fixed. *See Apotex*, 827 F.3d at 1063 (noting the "reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury"). The notice period ensures that the parties and the courts can litigate a preliminary injunction in an orderly fashion and with the deliberation it deserves, rather than racing through a TRO proceeding while products are being loaded into trucks.

Contrary to Sandoz's argument (Sandoz Br. 39-42), the purpose of the Act will not be served if notice is given prior to FDA licensing. That is because the

backbone of the Act is a system of litigation under which patent disputes often will not be fully resolved by the time the FDA licenses a biosimilar. The Act does obligate both parties to *identify* all patents that might be infringed by the biosimilar product described in the application. 42 U.S.C. § 262(*l*)(3). But not all such patents will be litigated prior to FDA licensure. Instead, the Act expressly directs the parties to narrow the original list of patents to only a subset that will be litigated in an immediate infringement action (and, indeed, it gives the biosimilar applicant ultimate control over how many patents will be part of that Round One suit).[8] All other patents are saved for a second round of litigation. Round Two can include, for example, patents whose litigation the parties have agreed to defer (for instance, because their relevance will not be clear until after the FDA completes its review); patents that the biologic pioneer wished to litigate earlier, but that the biosimilar applicant excluded through its control over Round One litigation; and patents that were issued to or licensed by the biologic pioneer after the parties exchanged their initial lists of patents, *see id.* § 262(*l*)(7).[9] The requirement of notice after FDA

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[8] *See id.* § 262(*l*)(4)-(6); *Apotex*, 827 F.3d at 1062 (noting that section 262(*l*) "gives the [biosimilar] applicant substantial authority to force … a limitation on the scope" of immediate litigation even of patents that the biologic pioneer "has good grounds to assert"); Sandoz Br. 39 (stating that the process set forth by the Biologics Act is "meant to narrow and allow [the biosimilar applicant] to control the scope of immediate litigation").

[9] Additionally, as Amgen notes, if the government is correct that § 271(e) does not establish an artificial act of infringement with respect to manufacturing process patents, those patents

licensure ensures that litigation over these categories of patents—as well as any patents that the parties have begun to litigate but whose resolution isn't yet determined at the time of licensure—can occur within a 180-day buffer period rather than on the eve of a biosimilar's entry into the market.

If (as Sandoz claims, Sandoz Br. 30-42) notice could come near the beginning of a biosimilar's approval process, the facts would be too contingent and undeveloped to allow meaningful consideration of the suitability and shape of injunctive relief. The parties would be arguing about the terms of a hypothetical injunction of a product that might not be approved for several years—if at all. And even if a license was eventually granted, it might look very different from the one the biosimilar applicant initially sought. Indeed, as Amgen notes, in this very case Sandoz's application was amended 30 times before FDA licensure. *See* Amgen Br. at 24.

Given the many unknowns prior to FDA licensure—including the uncertainty about when, if ever, a biosimilar product may be approved for sale—allowing statutory notice before FDA licensure is little better than requiring no notice at all. Premature notice would do nothing to remove the need for biologic pioneers to race to court after licensure to seek an immediate injunction. Nor would premature notice relieve district courts from making snap

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may not be eligible for inclusion in Round One, because the ambiguity about what (if any) license ultimately will issue may preclude declaratory judgment jurisdiction. *See* Amgen Br. 33-34; U.S. Br. 25.

judgments about the suitability and contours of injunctive relief in complicated cases. Sandoz's position, then, is not just countertextual; it also renders the Biologics Act incapable of solving a central problem Congress set out to address.

It bears repeating that no company is forced to take the shortcut that triggers the Act's notice requirement. If an applicant wants to avoid the disclosure and notice obligations imposed by the Act, it always has the right to prove the safety and efficacy of its drugs itself. But if an applicant elects to take the statutory shortcut by showing that its drug is biosimilar to an approved biologic, and if it receives approval for an FDA license, it must notify the pioneer at least 180 days before it begins selling. If it fails to give sufficient notice, a federal judge can enjoin it from going to market for up to 180 days. There is nothing novel or surprising about such a regime. It is a straightforward application of Congress's commands, which reflect an attempt to create a much-needed solution to the problem of drive-thru litigation of complex patents.

II. Nothing In The Act Overcomes The Presumption That Federal Courts May Award Any Appropriate Relief, Including Injunctive Relief.

Sandoz's position fares no better if it is recast from an argument about private rights of action into a claim that injunctive relief is unavailable to enforce the Biologics Act's notice requirement. *See* Sandoz Br. 44-45. Once the Court finds that biologic pioneers can sue to enforce the Biologics Act, the well-established

presumption is that the federal courts called upon to resolve such suits may order any appropriate relief, including injunctive relief. Any reluctance to recognize private rights of action falls away when it is time to consider forms of relief. That is because "'the question whether a litigant has a 'cause of action' is analytically distinct and prior to the question of what relief, if any, a litigant may be entitled to receive.'" *Franklin*, 503 U.S. at 69 (quoting *Davis v. Passman*, 442 U.S. 228, 239 (1979)).

Accordingly, in cases like this one, where the statutory scheme depends on private enforcement, the controlling authorities are "the long line of cases in which the Court has held that if a right of action exists to enforce a federal right and Congress is silent on the question of remedies, a federal court may order any appropriate relief." *Id.*; *see also Sullivan v. Little Hunting Park, Inc.*, 396 U.S. 229, 239 (1969) ("The existence of a statutory right implies the existence of all necessary and appropriate remedies."); *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946) ("Unless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of [its] jurisdiction.").

Sandoz, then, has it backwards. The drastic restriction of judicial authority that it urges would require a clear congressional mandate. Injunctive relief is available unless Congress has indicated otherwise. *See id.*; *see also Apotex*, 827 F.3d at 1064. And nothing in the Biologics Act suggests that Congress meant to "cabin [a federal court's] usual equitable powers." *United States v. Kwai Fun Wong*,

135 S. Ct. 1625, 1633 (2015). Every indication is that Congress intended for private parties to be able to seek injunctive relief in disputes over biologics. Whereas Sandoz needs to identify some clear basis to deny the federal courts' equitable powers, the Biologics Act points in the opposite direction.

The notice requirement and corresponding marketing limitation of § 262(*l*)(8)(A) are followed immediately (in § 262(*l*)(8)(B)) by a section called "Preliminary injunction." True to its name, that subsection explicitly authorizes injunctive relief. It provides that the pioneer "may seek a preliminary injunction prohibiting the [biosimilar] applicant from engaging in the commercial manufacture or sale of [its] biological product until the court decides the issue of patent validity, enforcement, and infringement" with respect to any Round Two patent. The subsection applies to situations in which the biosimilar applicant has provided notice of its intent to market. So on Sandoz's theory, Congress meant to authorize injunctive relief against an applicant that *did* comply with the notice requirement, but not against an applicant that did *not* comply. The Act provides no support for such an uneven reading, particularly given the presumption that equitable remedies are available unless Congress has indicated otherwise.

The role of the Biologics Act within the broader system of patent litigation further undermines the claim that Congress intended to roll back the equitable powers of the federal courts. Congress has expressly authorized courts to "grant injunctions in accordance with the principles of equity to prevent the

violation of any right secured by patent." 35 U.S.C. § 283. The Biologics Act's notice requirement protects those same rights from being undermined by the launch of an infringing biosimilar before a court has the opportunity to perform any serious analysis of what inevitably are complicated questions of patent law. The Act's careful framework allows a period of deliberation in which pioneers can seek injunctive relief without worrying that an applicant will violate their rights in the meantime. Temporary injunctions against commercial marketing and injunctions against patent infringement thus serve as complementary tools for protecting the same bundle of rights.

In attempting to carry its burden of showing that Congress intended to truncate the federal courts' equitable powers, Sandoz points to § 262(*l*)(9)(B). *See* Sandoz Br. 46. That section applies when a biosimilar applicant initially complies with the Act's requirements but later strays from the statutory path by, for example, failing to give the requisite notice before commercial marketing.[10] In that event, § 262(*l*)(9)(B) allows the biologic pioneer to seek "a declaration of infringement, validity, or enforceability" of certain patents—namely, those patents that the pioneer identified under § 262(*l*)(3)(A) as reasonable prospects for an infringement suit but that have not yet been litigated. According to Sandoz, this provision shows that

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[10] *See* 42 U.S.C. § 262(*l*)(9)(B) (cross-referencing § 262(*l*)(8)(A), which requires notice of commercial marketing, as well as subsections (*l*)(3)(B)(ii), (*l*)(5), (*l*)(6)(C)(i), and (*l*)(7)).

Congress meant to sweep away all other means of enforcing the notice requirement. Sandoz Br. 47.

But § 262(*l*)(9)(B) makes no attempt to address violations of the notice requirement. Allowing the adjudication of patent rights does not cure the harm that is created when the notice requirement is violated—namely, being forced into hasty patent litigation to stave off irreparable harm from market entry. *See supra* 17-20; *Apotex*, 827 F.3d at 1065 (explaining that the prospect of a declaratory judgment is "so gross a mismatch for the (8)(A) right that it cannot fairly be treated, in the absence of any statutory language so stating, as the exclusive remedy for (8)(A)'s violation").

Section 262(*l*)(9) plays a distinctive role within the framework of the Biologics Act. It provides that an applicant who follows the Act's rules enjoys temporary protection from declaratory-judgment suits based on patent rights. 42 U.S.C. § 262(*l*)(9)(A). Conversely, it makes clear that an applicant who breaks those rules is subject to such suits. *See id.* § 262(*l*)(9)(B). But in crafting this framework, Congress did nothing to limit courts' equitable powers to enforce violations of the notice requirement. "Nothing in paragraph (9) declares the exclusivity of the declaratory-judgment actions to which it refers .... There is no language that excludes other remedies for the conduct described." *Apotex*, 827 F.3d at 1064.[11]

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[11] Nor is this a case in which enforcing a statute by injunction would be "judicially unadministrable." *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1385 (2015). On the contrary, it is hard to imagine a simpler order than a prohibition

Sandoz also appeals to 35 U.S.C. § 271(e)(4), which it describes as showing "that patent-based remedies 'are the *only remedies* which may be granted by a court' for the artificial acts of infringement created by" the Act. Sandoz Br. 47 (italics added by Sandoz; underlining ours). This section is inapposite, because a violation of the notice provision is not an "artificial act[] of infringement created by" the Act. (By way of contrast, the filing of an abbreviated biosimilar application *is* an artificial act of infringement. *See* 35 U.S.C. § 271(e)(2)(C).) Thus, an injunction against commercial marketing in the absence of notice is not a remedy for artificial infringement, and § 271(e)(4) is facially inapplicable.

If anything, then, § 271(e)(4) underscores the flaws in Sandoz's interpretation. If Sandoz were correct that declaratory-judgment actions are the exclusive remedy for violations of the Act, that reading would have the effect of also foreclosing the "monetary and injunctive infringement remedies expressly authorized by 35 U.S.C. § 271(e)(4) for what is, after all, an infringement under § 272(e)(2)." *Apotex*, 827 F.3d at 1064. If Congress meant to foreclose patent damages, surely it would've said so. This is the very sort of elephants-in-mouseholes reasoning that Sandoz elsewhere decries. *See* Sandoz

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against commercial marketing until 180 days after notice is given. The Biologics Act itself furnishes all the language a court would need to craft its relief. *See* § 262(*l*)(8)(B) (discussing a preliminary injunction that prohibits an applicant "from engaging in the commercial manufacture or sale of" the biologic at issue).

Br. 33 (citing *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001)).

Sandoz comes no closer to carrying its burden of showing that Congress meant to displace the courts' equitable powers when it invokes § 262(*l*)(1)(H). That provision states that if a biologic pioneer discloses certain confidential information that it received from a biosimilar applicant, such disclosure will be "deemed to cause ... irreparable harm for which there is no adequate legal remedy." Sandoz says that this provision forecloses equitable relief to biologic pioneers for applicants' violations of the notice requirement. *See* Sandoz Br. 51-52. But this lone provision about confidentiality does not purport to address the separate questions of when and how biologic pioneers can enforce their *own* rights; it is only concerned with biosimilar applicants and the confidential data they provide. It is implausible to suggest that a provision dealing with breaches of confidentiality was secretly intended to shut the door to injunctive relief for entirely different harms.

Ultimately, Sandoz needs a clear indication from Congress to deny the equitable powers of the federal courts. *See Franklin*, 503 U.S. at 69; *Porter*, 328 U.S. at 398; *cf. United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496 (2001) ("[W]hen district courts are properly acting as courts of equity, they have discretion unless a statute clearly provides otherwise."); *eBay, Inc. v. MercExchange L.L.C.*, 547 U.S. 388, 391 (2006) ("As this Court has long recognized, 'a major departure from the long tradition of equity practice should not be lightly implied.'" (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305,

320 (1982))). The Biologics Act provides no such indication at all.

CONCLUSION

For the foregoing reasons, the Court should hold that injunctive relief is available if a biosimilar applicant does not provide the biologic pioneer with at least 180 days of notice between FDA licensing and commercial marketing, and if an applicant fails to disclose its biologics license application and related information to the pioneer.

Respectfully submitted,

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March 17, 2017

RECORD AND BRIEFS

FILED
MAR 17 2017
OFFICE OF THE CLERK
SUPREME COURT, U.S.

Nos. 15-1039, 15-1195

IN THE

Supreme Court of the United States

SANDOZ INC., PETITIONER,
v.
AMGEN INC., ET AL., RESPONDENTS

AMGEN INC., ET AL., CROSS-PETITIONERS,
v.
SANDOZ, INC., CROSS-RESPONDENT

ON WRITS OF CERTIORARI TO THE U.S. COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF *AMICUS CURIAE* FOR JANSSEN BIOTECH INC. SUPPORTING AMGEN INC.

March 17, 2017

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INTEREST OF *AMICUS CURIAE*

As a company that is actively engaged in discovering, developing and marketing innovative biological medicines, Janssen Biotech, Inc. ("Janssen")[1] has a strong interest in an interpretation of the Biologics Price Competition and Innovation Act ("BPCIA") that protects the balance the statute strikes between the respective interests of innovators and biosimilar applicants.

Janssen has a particularly strong interest in this case because Janssen is one of a relatively small number of biotechnology companies that have experience litigating under the BPCIA, which was enacted in 2010 but did not lead to litigation until late 2014. The suit before this Court was the first action filed under the BPCIA. *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15–cv–10698 (D. Mass.) ("*Janssen v. Celltrion*"), involving a proposed biosimilar version of Janssen's biological medicine Remicade®, was the second. In *Janssen v. Celltrion*, as here (and as in certain subsequent BPCIA actions), the biosimilar applicants did not fulfill their statutory obligation to disclose relevant information concerning their manufacturing processes, and they provided a premature notice of commercial marketing, before their biosimilar

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[1] No counsel for a party authored this brief in whole or in part and no person other than *amicus* and its counsel made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief, and those written consents are being submitted along with this brief.

product was licensed, that was recognized as ineffective after the Federal Circuit's decisions in this case and in *Amgen Inc. v. Apotex Inc.*, 827 F. 3d 1052 (Fed. Cir. 2016).

Janssen's interests as a major developer and manufacturer of new innovative biological medicines and its experience litigating patent infringement claims under the BPCIA may assist the Court in assessing the practical implications of the questions presented.

Janssen also submits this brief to highlight an important aspect of the Federal Circuit's decision below that contradicts arguments made by Sandoz, Inc., the Petitioner in No. 15-1039, and its *amici*. Sandoz argues that the "Federal Circuit turned [the] mere notice provision [of 42 U.S.C. § 262(*l*)(8)(A)] into a grant of 180 days of additional exclusivity for *all* biological products beyond the exclusivity period Congress expressly provided." Pet. Br. at i (emphasis added). But the Federal Circuit expressly disavowed that interpretation of its decision, holding that an "extra 180 days will *not* likely be the usual case" going forward. Pet. App. 22a (emphasis added); *accord Amgen v. Apotex*, 827 F. 3d at 1062. Janssen urges this Court to recognize, as the court did below, that neither party's position in No. 15-1039 requires deciding that 42 U.S.C. § 262(*l*)(8)(A) contemplates an extra 180 days of exclusivity for "all biological products."

INTRODUCTION AND SUMMARY OF ARGUMENT

As indicated by its name—the Biologics Price

Competition *and* Innovation Act—the BPCIA was enacted to create a pathway for approval of biosimilars that "balanc[es] innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010). Under the BPCIA, applicants are permitted to rely on research and clinical testing conducted by the innovator, often costing hundreds of millions of dollars, without any compensation to the innovator. Where an applicant chooses to take advantage of the innovator's research and clinical testing under the BPCIA, the statute requires the applicant to engage in a detailed patent dispute resolution process to ensure that the innovator's patent rights can be properly adjudicated. That process involves providing the innovator with full information disclosure at an early stage, negotiating in good faith over which patents should be litigated immediately, and notifying the innovator when the commercial marketing of a licensed product is imminent, so that the innovator has the opportunity to file a preliminary injunction motion prior to launch of the biosimilar. If the applicant does not want to participate in this process, it may forego relying on the innovator's data, conduct its own research, and file an ordinary biological license application.

1. The BPCIA requires that the biosimilar applicant "shall" provide a "notice of commercial marketing" no fewer than 180 days before the first commercial marketing of a "licensed" product, 42 U.S.C. § 262(*l*)(8)(A), so that the innovator may then "seek a preliminary injunction prohibiting the . . . applicant from engaging in the commercial manufacture or sale of such biological product." 42

U.S.C. § 262(*l*)(8)(B). The express statutory purpose of the notice is to trigger the innovator's right to seek a preliminary injunction. To satisfy this purpose, the requisite notice must be given *after* the FDA licenses the product for commercial marketing.

A notice that is issued months or even years before FDA approval of the biosimilar product—for example, contemporaneously with the filing of the applicant's abbreviated biologics license application ("aBLA")—is not a "notice of commercial marketing" in any meaningful sense. This kind of premature notice fails to serve the purpose of a "notice of commercial marketing" because it does not provide the innovator notice that commercial marketing is imminent, a prerequisite to a motion for a preliminary injunction under 42 U.S.C. § 262(*l*)(8)(B). A premature notice of commercial marketing leaves the innovator to guess when commercial marketing will actually begin and when the resulting irreparable harm will actually occur.

A premature notice of commercial marketing also leaves the innovator uncertain of the nature of the product that will finally be approved or whether the product will be approved at all. The diseases that a product will eventually be approved to treat, the methods of manufacture that will ultimately be approved, and even the precise composition of the product can change from those disclosed in the initial aBLA. Manufacturing processes are especially central to innovation in biotechnology because a biosimilar product is never identical to the innovator's product since they are produced from living cell lines. Even small changes in the

manufacturing process can produce significant differences in the safety and efficacy of the end product. Without knowing the indications for which a biological medicine is licensed, its final method of manufacture, or its precise composition, the innovator cannot identify exactly which of its composition, method-of-use, or method-of-manufacturing patents are infringed. In short, giving notice before FDA licensing of a product does not serve the statutory purpose of a "notice of commercial marketing." Indeed, since all biosimilar applicants hope to market their products eventually, such a notice serves no purpose at all.

Separately, and contrary to Sandoz's contention, the Federal Circuit's interpretation of section 262(*l*)(8)(A) does not extend the BPCIA's 12-year marketing exclusivity period by an "additional" 180 days, much less does it do so for "all" biological products. The relationship between statutory exclusivity and the notice of commercial marketing is not at issue here, because Amgen's Neupogen® product was approved more than 12 years before the BPCIA was enacted and therefore never enjoyed *any* statutory exclusivity at all. In a future case addressing the interaction between these two provisions of the BPCIA, the correct interpretation would be that the statutory exclusivity and notice periods can run concurrently. The BPCIA provides that a biosimilar license cannot be "made effective" for 12 years after the reference product was first approved, 42 U.S.C. § 262(k)(7)(A), but it does not prevent FDA from issuing an earlier approval with a delayed effective date, as it routinely does under similarly worded provisions of the Hatch-Waxman

Act. After such an early license decision, the approved product's composition, uses, and method of manufacture would be fixed, and the applicant could serve a notice of commercial marketing that would satisfy the statutory language and purpose. In such a case, the 180-day notice period would occur while the statutory period of exclusivity is still in effect.

2. This Court should also clarify that the information disclosure requirements beginning with 42 U.S.C. § 262(*l*)(2)(A) are mandatory and enforceable. They are not mere options that benefit only biosimilar applicants and can therefore be waived by biosimilar applicants at their sole discretion.

The Federal Circuit's interpretation of section 262(*l*)(2)(A) effectively guts the statute's disclosure provisions, and transforms a carefully orchestrated dispute resolution process into a series of strategic choices available only to biosimilar applicants. Under the Federal Circuit's incorrect reading, a biosimilar applicant can avail itself of the innovator's proprietary data in seeking an FDA license on a biosimilar product under the BPCIA, while ignoring the *quid pro quo* for doing so—i.e., the statutory requirement that the applicant must provide information needed for the innovator to assess potential patent infringement and protect its patent rights.

The BPCIA does not offer the biosimilar applicant the choice between participating in or declining to participate in the statutory patent dispute resolution procedures. Instead, Congress offered biosimilar applicants a choice between: (a) using the innovator's

FDA license and underlying research and engaging in the BPCIA's mandatory information exchange process, or (b) foregoing reliance on the innovator's clinical research and instead conducting its own expensive research. The statutory price for using the simpler, less expensive route is compliance with mandatory procedures requiring the applicant to share with the innovator information that otherwise would be private, including the aBLA and details of the applicant's manufacturing processes. This information is needed so that the innovator can assess potential patent infringement and, where appropriate, institute litigation prior to biosimilar launch to protect its patent rights. If the applicant avails itself of the innovator's FDA license and underlying research, then the BPCIA's disclosure requirements are mandatory and enforceable. The Federal Circuit's holding that those requirements are optional and unenforceable is at odds with the BPCIA and upsets the balance that Congress intended.

Section 262(*l*)(2)(A) states that a biosimilar applicant "shall" make the disclosures at issue in this case. The mandatory nature of this obligation is underscored by Congress's use of the permissive "may" in other statutory provisions, when an optional meaning was intended. In Janssen's view, the issue presented is simple: When a biosimilar applicant chooses to use the benefits of the BPCIA and piggyback on the innovator's work, is it bound to play by the rules? Janssen believes the answer is yes.

ARGUMENT

I. AN APPLICANT DOES NOT SATISFY ITS OBLIGATION TO PROVIDE "NOTICE OF COMMERCIAL MARKETING" BY PROVIDING SUCH NOTICE BEFORE ITS BIOSIMILAR PRODUCT IS LICENSED BY THE FDA

The Federal Circuit was correct in holding that an applicant does not satisfy its statutory obligation to provide "notice of commercial marketing" under 42 U.S.C. § 262(*l*)(8)(A) by giving notice before the FDA licenses the applicant's biosimilar product. Pet. App. 20–23a. A notice given earlier is "premature and ineffective." *Id.* 23a.

A. Under Section 262(*l*)(8), a Notice of Commercial Marketing Cannot Precede Licensing

42 U.S.C. § 262(*l*)(8) is entitled "NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION." Under this section, an applicant is obligated to provide a notice of commercial marketing of a "licensed" product, and receipt of that notice entitles the innovator to seek a preliminary injunction to protect against imminent harm from sales of the licensed product.

1. Under Section 262(*l*)(8)(A), a "Notice of Commercial Marketing" Relates to a Product that Has Been Licensed and Can Be Commercially Marketed

The text of section 262(*l*)(8)(A) makes clear that an effective notice of commercial marketing can only be given after the product has been licensed. That

conclusion follows from the use of the term "licensed" in section 262(*l*)(8)(A) and from the term "notice of commercial marketing" in the title of that subsection.

The term "licensed": Section 262(*l*)(8)(A) states that an applicant shall give the innovator 180-days' notice of the "first commercial marketing of the biological product *licensed under subsection (k)*." 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). A "biological product licensed under subsection (k)" is one that is licensed—not one that may (or may not) be licensed at some indeterminate time in the future.

Sandoz argues that term "licensed under subsection (k)" in section 262(*l*)(8)(A) "merely refers to the applicant's proposed biosimilar product, which will be 'licensed' by the time of marketing." Sandoz Br. 27. The Government echoes that argument, asserting that "licensed" in section 262(*l*)(8)(A) "describ[es] the biological product as of 'the *date* of [its] first commercial marketing.'" United States *Amicus* Br. 29 (emphasis and bracketed language added by the Government). That interpretation distorts the statutory language. Under this approach, the phrase "licensed under subsection (k)" is a nullity because "first commercial marketing of the biological product *licensed under subsection (k)*" would mean the same thing if the italicized words were not part of the statute. This approach thus violates a "cardinal principle of statutory construction," i.e., the principle that courts must "'give effect, if possible, to every clause and word of a statute.'" *Duncan v. Walker*, 533 U.S. 167, 174 (2001); *see also TRW, Inc. v. Andrew*, 534 U.S. 19, 31 (2001) ("It is 'a cardinal principle of statutory

construction' that 'a statute ought, upon the whole, be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void or insignificant.").

A marketed biosimilar product certainly must be licensed, but it does not follow that Congress would describe an unlicensed product as "licensed" whenever its future commercial marketing is being discussed. On the contrary, other related provisions of the BPCIA referring to the future commercial marketing of a yet-to-be-licensed product do not use the term "licensed product," and instead make clear that the product that will eventually be commercially marketed is not yet licensed.

The provision of the BPCIA that addresses patent disputes, section 262(*l*), refers to future "commercial marketing" three times outside of subsection (*l*)(8). On none of these occasions does the statute use the term "licensed product" to refer to the unlicensed product that may be licensed and marketed in the future. For example, the statute requires the applicant, if it intends to market its biosimilar product before the expiration of a patent, to provide a detailed statement describing its opinion that "such patent is invalid, unenforceable, or will not be infringed by the *commercial marketing of the biological product that is the subject of the subsection (k) application.*" 42 U.S.C. § 262(*l*)(3)(B)(ii)(I) (emphasis added). If, on the other hand, the applicant does not challenge a patent, it is required to provide a statement that it "does not intend to begin *commercial marketing of the biological product* before the date that such patent

expires." 42 U.S.C. § 262(*l*)(3)(B)(ii)(II) (emphasis added). After the applicant provides these statements, the innovator (if it wishes to assert a disputed patent) must describe its opinion that "such patent will be infringed by the *commercial marketing of the biological product that is the subject of the subsection (k) application.*" 42 U.S.C. § 262(*l*)(3)(C) (emphasis added).

Congress's use of different terminology in section 262(*l*)(8)(A)—referring to the "commercial marketing of the biological product *licensed* under subsection (k)"—indicates that Congress was referring to a product that already has been licensed by the FDA.[2]

The term "notice of commercial marketing": Congress's use of the term "notice of commercial marketing" in the title of section (8)(A) confirms that the notice in question refers to a product that has been licensed and could be marketed. In any meaningful sense of the words, a "notice of commercial marketing" can only be given *after* a biological product is licensed, because a biological

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[2] *See Abbott v. Abbott*, 560 U.S. 1, 33 (2010) ("In interpreting statutory text, we ordinarily presume that the use of different words is purposeful and evinces an intention to convey a different meaning."); *Sebelius v. Cloer*, 569 U.S. __, __, 133 S. Ct. 1886, 1894 (2013) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (alteration and internal quotation marks omitted).

product cannot be commercially marketed before it is licensed. It would be superfluous for an applicant to give "notice," prior to obtaining a license, that it intends to commercially market its product once it obtains a license; that is the sole purpose of submitting a license application. If the notice required by section 8(A) was not intended to describe a product that could be commercially marketed, as Sandoz contends, then Congress would not have described that notice as a "notice of commercial marketing."

2. The Purpose of a Notice of Commercial Marketing is Defeated If the Notice Is Served Before a Product is Licensed

Sandoz's interpretation also violates another basic principle of statutory interpretation, i.e., the principle that courts must interpret statutes "'as a symmetrical and coherent regulatory scheme,' and 'fit, if possible, all parts into an harmonious whole.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citations omitted).

The other subsections of section 262(*l*)(8) confirm that a notice of commercial marketing must follow licensing, not precede it. A notice of commercial marketing of "the biological product licensed under subsection (k)," 42 U.S.C. § 262(*l*)(8)(A), triggers the innovator's right under section 262(*l*)(8)(B) to "seek a preliminary injunction" prohibiting the applicant from "engaging in the commercial manufacture or sale of such biological product" while the suit is pending. 42 U.S.C. § 262(*l*)(8)(B). Section 262(*l*)(8)(C) requires the parties to "reasonably cooperate" to expedite further discovery "in

connection with the preliminary injunction motion." 42 U.S.C. § 262(*l*)(8)(C).

As its name indicates, a "notice of commercial marketing" under section 262(*l*)(8)(A) is designed to inform the innovator that the applicant will soon begin commercial marketing of a licensed product. Armed with that information, the innovator is then in a position to move for a preliminary injunction under section 262(*l*)(8)(B). Any other reading is contrary to section 262(*l*)(8)'s language and structure.

In general, a preliminary injunction is not available unless the harm in question—in this case, the harm from commercial marketing—is imminent. It is not available "simply to prevent the possibility of some remote future injury." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). Rather, a plaintiff "must show that the injury complained of is of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm." *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (emphasis removed); *see also Connecticut v. Massachusetts*, 282 U.S. 660, 674 (1931) ("Injunction[s] issue[] to prevent existing or presently threatened injuries. One will not be granted against something merely feared as liable to occur at some indefinite time in the future."). The requirement under section 262(*l*)(8)(A) that the product has been licensed ensures the imminence necessary to vindicate the right to move for a preliminary injunction under section 262(*l*)(8)(B).

Treating a pre-license notice as an effective "notice of commercial marketing" under section

262(*l*)(8) would sever that section's explicit linkage between the notice and the innovator's ability to seek a preliminary injunction. If an applicant could file an effective notice of commercial marketing prior to licensing, for example at the time it filed its aBLA (which may be years before approval), then the notice would serve no purpose at all because the time of commercial launch would be entirely speculative and not imminent. The notice would not serve its statutory purposes of announcing an imminent launch and the accompanying need to consider a preliminary injunction, and the innovator would be deprived of the benefit the notice was intended to provide.

In addition, a "notice of commercial marketing" that is served before FDA licensing does not give the innovator any information that the innovator does not already have. The applicant's aBLA, which must be supplied to the innovator within 20 days of FDA's acceptance of the aBLA for review, *see* 42 U.S.C. § 262(*l*)(2), already puts the innovator on notice that the applicant has applied for FDA approval and intends to market a biosimilar if an FDA license is obtained. A "notice of commercial marketing" that is served before the product is actually licensed does not provide any additional information.

3. Requiring a Notice of Commercial Marketing to Come After Licensing Ensures that the Nature of the Controversy Will Be Concrete

The requirement that a notice of commercial marketing must follow licensing also serves another important purpose. As the Federal Circuit

recognized, it ensures the existence of a "fully crystallized controversy regarding the need for injunctive relief" at the time the reference product sponsor is faced with the decision whether to move for a preliminary injunction. Pet. App. 21a. In particular, "[t]he 180-day period gives the [innovator] time to assess its infringement position for the final FDA-approved product as to yet-to-be-litigated patents." *Amgen v. Apotex*, 827 F.3d at 1063. Until the aBLA is approved, the innovator cannot know which of its patents will be infringed by the marketed product. Without a post-licensing window in which to assess the need for injunctive relief, innovators will be obliged to bring protective preliminary injunction motions that could have been avoided.

As the Federal Circuit pointed out, prior to licensing, key features of the proposed product may be unknown and subject to change, *e.g.*, the approved therapeutic uses for the product, the approved dosage regimen, the approved method of administration, and the approved methods of manufacture. *See* Pet. App. 21a. Even the precise structure of the biosimilar product is potentially subject to change.[3] Until the patentee knows this

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[3] *See, e.g.*, Nana Kawasaki et al, *The Significance of Glycosylation Analysis in Development of Biopharmaceuticals*, Biol. Pharm. Bull. 32(5) 796, 798 (2009) (noting that "changes in manufacturing processes for biopharmaceuticals are often attempted during the development phase and after marketing authorization" and that "changes in the manufacturing process possibly cause the alteration of glycosylation in . . . glycoprotein products," which include many biologics).

information, it will not know the relevance of certain patents—*e.g.*, patents on methods of using the product for therapeutic purposes that may or may not be approved, or on processes that may or may not be used in the ultimate commercial product, or even on the composition of the product. There may also be patents that will expire before licensing or within 180 days of licensing, which need not be litigated if notice of commercial marketing is provided after a license is obtained. The 180-day post-licensing "statutory window" enables the innovator to wait until licensing to decide whether to bring a motion for injunctive relief—and thus potentially avoid the need for such a motion altogether. Pet. App. 21a.

Janssen's experience in *Janssen v. Celltrion* illustrates that these considerations are not speculative, but real. In that case, Janssen filed suit asserting a number of patents based on Celltrion's application to market a biosimilar version of Janssen's Remicade (infliximab) biologic. Like Sandoz here, Celltrion served a premature notice of commercial marketing (in February 2015), before the biosimilar product was licensed and at a time when the date of eventual licensing, if any, was unknown. One month later, before the Federal Circuit issued its decision below, Janssen moved for a preliminary and permanent injunction to enforce section 262(*l*)(8)(A), contending (as Amgen did here) that the statute requires a mandatory, post-approval 180-day period to assess patent rights. Janssen felt compelled to bring the motion because Celltrion claimed the right, based on its pre-license notice of commercial marketing, to launch commercially in as few as 180 days should its biosimilar product be

approved by then. Had a claim under section 262(*l*)(8)(A) not been available, Janssen likely would have been forced to protect its rights by moving prematurely for a preliminary injunction on one or more of its patents.

As it turned out, an unforeseeable delay in the approval process, coupled with the defendants' agreement to observe a 180-day post-license notice period in light of the Federal Circuit's decisions in this case and in *Amgen v. Apotex*, *supra*, made such a motion for a preliminary injunction unnecessary. The unnecessary motion was avoided for the very reasons identified by the Federal Circuit in this case.

For example, as the Federal Circuit pointed out, a post-approval window for patent assessment is important because the "therapeutic uses" for a proposed biosimilar are not "fixed" prior to FDA licensing. Pet. App. 21a. In *Janssen v. Celltrion*, Celltrion sought approval for its biosimilar for use in treating many therapeutic indications, including Crohn's disease. For a variety of reasons, it was uncertain whether Celltrion's biosimilar would be approved for treating Crohn's disease (it had not been in Canada), and there was no reason for Janssen to allege infringement of a patent covering methods of treating Crohn's disease unless the FDA approved Celltrion's biosimilar for treating Crohn's disease. Before Celltrion's biosimilar product was licensed, there was no way for Janssen to assess the need to assert that patent, much less rely on it in seeking a preliminary injunction under section 262(*l*)(8)(A).

Ultimately, the FDA did approve Celltrion's biosimilar for use in treating Crohn's disease, but that approval did not come until April 2016, only two months before the Crohn's disease patent expired. When Celltrion served its initial notice of commercial marketing—over a year before FDA licensing—the timing of that approval could not have been predicted. In view of the Federal Circuit's holding in this case and *Amgen v. Apotex* that section 262(*l*)(8)(A) creates a 180-day post-license window before commercial marketing can commence, Celltrion agreed to delay launching its product until after the patent expired and Janssen did not need to move for a preliminary injunction. As a result, the Federal Circuit's holding in this case spared the parties and the district court the wasted time of an unnecessary preliminary injunction motion.

Another patent asserted in *Janssen v. Celltrion* similarly illustrates the importance of a notice of commercial marketing coming after FDA licensing. One of Janssen's patents expired on September 15, 2015, within the earliest post-approval 180-day period anticipated at the time that Janssen filed suit. Under Janssen's reading of the BPCIA, there was never any need to seek emergency relief on this patent because commercial launch could not occur before patent expiration. If Sandoz's reading of the BPCIA were to prevail, however, future innovators in similar circumstances may be obliged to seek a premature preliminary injunction to protect against the possibility of FDA approval and commercial launch, even if it were also possible that the patent would expire by the time of actual FDA approval.

For Janssen to have moved for a preliminary injunction would have been a burden on the judicial system and a waste of resources for all involved. Yet if Celltrion had been permitted to serve a pre-license notice of commercial marketing, Janssen would likely have been forced to do so. Under the interpretation put forth by Sandoz, a biosimilar applicant could launch its product on the very same day that it receives FDA approval, leaving the innovator no "period of time to assess and act upon its patent rights." Pet. App. 26a. The innovator would thus find itself between a rock and a hard place, having to choose between a burdensome and potentially unnecessary pre-launch motion for a preliminary injunction or accepting the irreparable harm of a biosimilar launch. As the Federal Circuit correctly held, the purpose of section 262(*l*)(8)(A) was to avoid this dilemma.

A proper construction of the notice provision allows the patentee to seek a preliminary injunction on any or all of its relevant patents based on the facts available at the time of FDA license, while providing a protected statutory window in which the court and the parties can fairly assess the parties' rights prior to launch. Sandoz's position would thwart that opportunity.

4. The Correct Interpretation of Section 262(*l*)(8) Does Not Extend the Statutory Exclusivity Period

Sandoz and its *amici* contend that requiring licensing to precede a notice of commercial marketing under § 262(*l*)(8)(A) would "mean[ ] that sponsors receive 12 and one-half years of exclusivity

from biosimilar competition, rather than the 12 years Congress intended." Sandoz Br. 7. According to Sandoz "[t]his would be true for every single biosimilar." *Id.* But this case does not present the question whether section 262(*l*)(8)(A) extends exclusivity beyond the 12 years provided by 42 U.S.C. § 262(k)(7)(A), much less whether it does so for "every single biosimilar." If that question were to arise in the future, the answer would likely be that the exclusivity period of section 262(k)(7)(A) and the notice period of section 262(*l*)(8)(A) can run concurrently.

The interaction between the 12-year exclusivity provision and the 180-day notice is not at issue in this case because Amgen never had the opportunity to receive *any* period—much less 12 or 12½ years—of statutory exclusivity for Neupogen. The reason is that Neupogen (like the other biologics that are currently subject to biosimilar applications) is an older biologic which was on the market more than 12 years before the biosimilar application was filed. Such products do not enjoy any statutory period of non-patent exclusivity under the BPCIA; indeed, biosimilar applications for Neupogen and similarly situated products could be filed immediately once the statute went into effect. For such products, the only protection provided by the BPCIA is the modest 180-day period after licensing for an innovator to bring a potential preliminary injunction motion.

The issue here is whether a notice of commercial marketing must follow licensing of the biosimilar product, not whether the 180-day notice period runs consecutively with the statutory exclusivity period.

If that question arises in a future case, the better reading of the statute is that the two periods typically can run concurrently, since the statute indicates that a license may be *approved* (although not *made effective*) while the statutory exclusivity is still in effect. During the statutory period of market exclusivity, "[a]pproval of a[] [biosimilar] application . . . may not be *made effective*." 42 U.S.C. § 262(k)(7)(A) (emphasis added); *see also id.* § 262(a)(1)(A) (providing that no person may sell a biologic in the United States unless a "biologics license under this subsection or subsection (k) *is in effect*") (emphasis added). This language indicates that FDA may approve the application before the 12-year mark, effective upon the expiration of the market exclusivity period. If the product is approved while the statutory exclusivity period is in effect, the condition precedent to a notice of commercial marketing is met, and the market exclusivity and the 180-day notice period may run concurrently.

Two panels of the Federal Circuit, including the panel in this case, have endorsed this reading of the statute and rejected Sandoz's argument that a post-license notice entails extending the statutory exclusivity period. The court of appeals in this case reasoned (correctly) that "requiring FDA licensure before notice of commercial marketing does not necessarily conflict with the 12-year exclusivity period of § 262(k)(7)(A)." Pet. App. 22a. "It is true that in this case . . . Amgen will have an additional 180 days of market exclusion after Sandoz's effective notice date; that is because Sandoz only filed its aBLA 23 years after Amgen obtained FDA approval of its Neupogen product. . . . That extra 180 days

will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." *Id.*

Similarly, in *Amgen v. Apotex*, a different panel held that the BPCIA does not provide any "reason that the FDA may not issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date—a possibility suggested by [42 U.S.C] § 262(k)(7)'s language about when the FDA approval may 'be made effective.'" *Amgen v. Apotex*, 827 F.3d at 1062. The 180-day notice of commercial could be sent "as soon as the license issues, even if it is not yet effective." *Id.* A notice sent in this fashion would not extend the 12-year exclusivity period and would not delay commercial launch.

Sandoz's arguments against the Federal Circuit's reasoning are unpersuasive. Sandoz Br. 58-60. Sandoz cites a draft guidance document in which FDA states in passing that it cannot license biosimilar products during the statutory exclusivity period, *id.* at 58-59, but this document does purport to deny that an early license can be issued with a later effective date. To the contrary, it echoes the statutory language, stating that "[s]pecifically, approval of a 351(k) application may not be *made effective* until 12 years after the date of first licensure of the reference product."[4]

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[4] Draft Guidance, FDA, *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351 of the PHS Act* (Aug. 2014) at 2 (emphasis added), available at https://www.fda.gov/downloads/drugs/guidancecompliance%20regulatoryinformation/guidances/ucm407844.pdf.

Sandoz also points to the Hatch-Waxman Act, contending that since that statute expressly refers to "tentative approvals," the BPCIA cannot allow for early license decisions with delayed effective dates without using that term. Sandoz Br. 59-60. But the Hatch-Waxman Act supports the Federal Circuit's reading of the BPCIA. The statutory provision Sandoz cites is merely the definition of "tentative approval," a term that is used in connection with forfeiture of the exclusivity period for the first generic applicant. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd); *id.* §§ 355(j)(5)D)(i)(I)(bb) & 355(j)(5)D)(i)(IV). The provisions that affirmatively authorize FDA to issue approvals with delayed effective dates do not use the term "tentative approval." Rather, they use language virtually identical to that in the BPCIA: They refer to the dates that "approval of an application . . . shall be made effective." *E.g.*, 21 U.S.C. § 355(c)(3). Given that the BPCIA was modeled on the Hatch-Waxman Act, its drafters would have understood that referring to when a license may (or may not) or "be made effective" means that there can be a separation between the license decision and the effective date.

So construed, the 180-day period would not delay commercial marketing unless a license issues after the 12-year period has expired. In that situation, the only one presented here, the 180-day notice period is the only window available to the innovator to avoid irreparable harm by litigating its patents before market launch. There is no basis in the statute to deny that modest protection to the innovator.

B. The 180-Day Notice Is Not Optional and May Be Enforced by the Courts

The obligation to provide 180-day notice of commercial marketing is framed in language that is mandatory and imperative. *See* 42 U.S.C. § 262(l)(8)(A) ("The subsection (k) applicant *shall* provide notice . . . .") (emphasis added). The duty to provide such notice is not optional.

District courts plainly have authority to enforce compliance with the notice provision by issuing an appropriate preliminary injunction. The notice requirement requires the applicant to provide notice no later than 180 days "before the date of the first commercial marketing." 42 U.S.C. § 262(l)(8)(A). If an applicant attempts to launch a biosimilar product fewer than 180 days after an effective notice is given, a federal court in an appropriate action has the power to maintain the status quo by preliminarily enjoining commercial marketing during the 180-day notice period. It would defeat section 262(*l*)(8)(A)'s basic purpose, and be directly contrary to its terms, if a biosimilar applicant could not be prevented from marketing before the expiration of the 180-day period. Clearly, for example, an applicant that served a 180-notice of commercial marketing and then sought to launch on day 90 could be enjoined from doing so. So too can an applicant that seeks to commercially market its product before providing an effective notice of commercial marketing.

Indeed, the premise of the statute is that the innovator will be irreparably harmed if denied that 180-day period window after licensing to bring a preliminary injunction. That premise can only be

enforced with an injunction. *See, e.g., City of New York v. Golden Feather Smoke Shop*, 597 F.3d 115, 120 (2d Cir. 2010) ("In certain circumstances, [courts] . . . employ a presumption of irreparable harm based on a statutory violation."); *Miller ex rel. S.M. v. Bd. of Educ.*, 565 F.3d 1232, 1252 n.13 (10th Cir. 2009) (statutory provision requiring maintenance of status quo during pendency of proceedings imposes "an automatic statutory injunction" on parties) (quoting *Norman K. ex rel. Casey K. v. St. Anne Cmty. High Sch. Dist. No. 302*, 400 F.3d 508, 510-11 (7th Cir. 2005)).

Although the BPCIA permits the innovator to commence a declaratory judgment action if the applicant "fails to complete" any of several steps, including the 180-day notice required by section 262(*l*)(8)(A), "there is no [statutory] language that excludes other remedies for the conduct described." *Amgen v. Apotex*, 827 F.3d at 1064. As part of its power to protect its jurisdiction and supervise BPCIA patent litigation, a court can properly require compliance with the notice provision to provide an opportunity for the innovator to move for a preliminary injunction before the biosimilar product is commercially marketed, as contemplated by the statute. *See, e.g., FTC v. Dean Foods Co.*, 384 U.S. 597, 604 (1966) (the All Writs Act creates "power to issue injunctions to preserve the status quo").[5]

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[5] Because courts in BPCIA patent infringement actions have the power to enforce section 262(*l*)(8)(A), Janssen agrees with Amgen that the Court need not address whether that provision provides a private right of action. Amgen Br. 25, 43-45.

II. SECTION 262(*l*)(2)(A)'S DISCLOSURE REQUIREMENT IS MANDATORY AND ENFORCEABLE BY THE COURTS

Section 262(*l*)(2)(A) of the BPCIA uses mandatory language in stating that an applicant "*shall provide* to the [innovator] a copy of the [aBLA] . . . and such other information that describes the process or processes used to manufacture the biological product" that is the subject of an application for approval under the statute. 42 U.S.C. § 262(*l*)(2)(A) (emphasis added). By statute, the applicant must provide this information at the outset of the approval process, "[n]ot later than 20 days" after the applicant is notified that its application has been accepted for review. 42 U.S.C. § 262(*l*)(2). Although Congress framed this disclosure requirement in "language of an unmistakably mandatory character," *Hewitt v. Helms*, 459 U.S. 460, 471 (1983), the Federal Circuit concluded that "'shall' in section 262(*l*)(2)(A) does not mean 'must,'" but means that the applicant may optionally disclose the required information. Pet. App. 15a. The BPCIA does not support that conclusion.

As Justice Holmes famously observed, compliance with the law is *always* optional. A party may choose to honor a contract, but a "bad man" may choose to breach the contract and pay damages instead. Oliver W. Holmes, *The Path of the Law*, 10 Harv. L. Rev. 457, 459-62 (1897). In that sense, the BPCIA is like any other law: It presents biosimilar makers with a choice between complying with the statute or suffering the consequences. But that reductive mode of analysis skips over the critical first step. Does the

law on its face invite a choice, or is the real choice between following the law or violating it? That predicate question must be answered before considering the consequences of one choice or another.

A. The Disclosures Required by Section 262(*l*)(2)(A) Are Mandatory

Section 262(*l*)(2)(A)'s disclosure requirement is expressed in language that is mandatory and imperative: The disclosures described in that section "shall [be] provide[d]." 42 U.S.C. § 262(*l*)(2)(A). "The word 'shall' generally indicates a command that admits of no discretion on the part of the person instructed to carry out the directive." *National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661–62 (2007) (citation omitted). Other sections of the BPCIA reinforce the mandatory nature of this obligation by referring to "the information that is *required* to be produced pursuant to paragraph [*l*](2), 42 U.S.C. § 262(*l*)(1)(B)(i), and "information *required* under paragraph [*l*](2)(A)," 42 U.S.C. § 262(*l*)(9)(A) (all emphases added). *See also* 42 U.S.C. § 262(*l*)(9)(C) (same). "Congress could not have chosen stronger words to express its intent that [disclosure] be mandatory in cases where the statute applied . . . ." *United States v. Monsanto*, 491 U.S. 600, 607 (1989). Congress also used the mandatory "shall" in other sections of the BPCIA that address patent dispute resolution provisions. *See, e.g.*, 42 U.S.C. § 262(*l*)(3)(A), (*l*)(3)(B), (*l*)(3)(C), (*l*)(4)(A).

In contrast, where Congress wanted a particular step to be optional or conditional, the BPCIA states that a party "may" take such action. For example,

the section immediately following section 262(*l*)(2)(A) states that the applicant "*may provide* to the reference product sponsor additional information requested by or on behalf of the [innovator] . . . ." 42 U.S.C. § 262(*l*)(2)(B); *see also* 42 U.S.C. § 262(*l*)(3)(B)(i) (stating that the applicant "*may provide* to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted . . . .") (all emphases added). "[W]hen a statute distinguishes between 'may' and 'shall,' the latter generally imposes a mandatory duty," *Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1972 (2016), and there is "no reason to depart from the usual inference here." *Id.* at 1977. "[Where] the word 'may' is used in special contradistinction to the word 'shall,'" there can be no reason for taking "a liberty . . . with the plain words of the statute." *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359–60 (1895).

In the Federal Circuit's view, a failure to meet section 262(*l*)(2)(A)'s disclosure requirements "did not violate the BPCIA" because the BPCIA "explicitly contemplate[s]" the possibility of noncompliance. Pet. App. 15a. That is a *non sequitur*. Obligations imposed by statute do not become optional merely because the statute contemplates the possibility of a violation. For example, the obligation to file income tax returns under 26 U.S.C. § 6012 does not become optional because Congress addressed the consequences of failing to file. *See* 26 U.S.C. § 7203. Likewise, the obligations of security issuers to disclose certain information to the public and the S.E.C. do not become optional merely because a

failure to disclose the required information has statutory consequences. *See* 15 U.S.C. § 78m. By the same token, the disclosures required by the BPCIA do not become optional merely because the statute contemplates the possibility that an applicant may violate the statute.

Under the Federal Circuit's reasoning, the disclosures required by section 262(*l*)(2)(A) are optional in a way that is grossly one-sided: only the biosimilar applicant is given any meaningful option. Because the statutory process begins with the applicant's provision of information to the innovator, 42 U.S.C. § 262(*l*)(2)(A), it is the applicant, not the innovator, who supposedly may opt to forego the process. If the applicant initiates the BPCIA process and completes it, the innovator must participate or risk losing its right to seek lost profit damages, potentially worth billions of dollars. *See* 35 U.S.C. § 271(e)(6). The Federal Circuit's interpretation effectively transforms the BPCIA's carefully balanced process into a one-sided option that favors only the applicant.

The disclosure provisions set forth in section 262(*l*)(2)(A) are intended to benefit both parties and the courts by allowing innovators to assess an applicant's documentary evidence first and then file suit asserting infringement of patents where the documentary evidence provides a reasonable basis for that assertion. That purpose is frustrated if an applicant violates section 262(*l*)(2)(A)'s disclosure provisions. If the applicant does not provide the disclosure that section 262(*l*)(2)(A) requires, then the innovator is left in the situation of having to sue first

and obtain documentary evidence concerning the applicant's product and manufacturing process later. In that scenario, suit would be brought on *all* patents where there is a possibility of infringement and the action subsequently would be winnowed down to only those patents where the initial allegations are consistent with later-provided facts.

That is exactly what happened in the *Janssen v. Celltrion* case. Because the applicants there did not provide all the information required under section 262(*l*)(2)(A) at the outset, Janssen initially was forced to assert several manufacturing process patents that Janssen ultimately dropped from the case when it later turned out that Celltrion was using a different process. This was because, as is almost always the case, an owner of a manufacturing process patents cannot determine if they are being infringed until the defendant discloses information specifying the details of its manufacturing process, as required under section 262(*l*)(2)(A). Janssen would have had no need to assert those patents if the applicant had provided the required disclosures at the outset. *Janssen v. Celltrion* thus illustrates how violations of section 262(*l*)(2)(A)'s disclosure requirements harm the public and unnecessarily burden the courts and the innovator by leading to litigation that could have and should have been avoided or minimized if the applicant had met section 262(*l*)(2)(A)'s disclosure requirements at the outset.

The *Amgen v. Hospira* case, currently on appeal to the Federal Circuit, further illustrates the problem. In that case, the biosimilar applicant

(Hospira) failed to provide manufacturing information to the innovator (Amgen) at the outset. Appellant's Br. 8-10, Dkt. 28, No. 2016-2179 (Fed. Cir. Sept. 12, 2016). In subsequent litigation, the district court denied Amgen's request for discovery concerning Hospira's manufacturing process as not relevant to any patent on which Amgen had sued. The only way Amgen could have avoided that result would have been by asserting patents before having the information needed to assess whether they are infringed. If Hospira had complied at the outset with section 262(*l*)(2)(A), Amgen would have had all the information and been able to assess which of its patents are infringed before bringing suit.

The BPCIA procedures are not intended to benefit the applicant alone, but rather to benefit the courts and the innovators as well by creating an orderly process for identifying and litigating potentially infringed patents before a proposed biosimilar is marketed. Failing to provide the required disclosures at the outset defeats that statutory purpose.

Because the disclosure requirements in section 262(*l*)(2)(A) are not for the sole benefit of the applicant, an applicant does not have the right to unilaterally waive the requirements of that paragraph. It is true that a "party may waive any provision, either of a contract or of a statute, *intended for his benefit.*" *United States v. Mezzanatto*, 513 U.S. 196, 201 (1995) (quoting *Shutte v. Thompson*, 82 U.S. 151, 159 (1873)) (emphasis added). But logically, this rule cannot

apply to a "provision that benefits both sides." *Citadel Equity Fund Ltd. v. Aquila, Inc.*, 168 F. App'x 474, 476 (2d Cir. 2006).[6] The Federal Circuit erred in concluding that the biosimilar applicant may opt out of its provisions.

B. Courts May Enforce Compliance With Section 262(*l*)(2)(A)'s Disclosure Requirements

Once one recognizes that section 262(*l*)(2)(A)'s disclosure provisions are mandatory, not optional, the next question is what remedies are available to enforce those provisions. This question focuses on how to treat Justice Holmes' "bad man," i.e., an entity that has violated an obligation imposed by statute—not a citizen who is simply making an acceptable choice offered by the law.

As the Federal Circuit recognized, if an applicant does not disclose the information identified in section 262(*l*)(2)(A), the BPCIA authorizes the innovator to bring suit "under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)."[7] Pet. App. 15a. The

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[6] *Accord Shared Imaging, Inc. v. Campbell Clinic, Inc.*, No. 98-5366, 1999 U.S. App. LEXIS 6356, at *13 (6th Cir. Apr. 2, 1999) ("Of course, one party cannot unilaterally waive a provision that benefits the other party to the contract."); *LeaseAmerica Corp. v. Norwest Bank Duluth, N.A.*, 940 F.2d 345, 348 (8th Cir. 1991) (same).

[7] Under the first provision, the innovator (but not the applicant) "may bring an action under section 2201 of title 28 for a declaration of infringement,, validity or enforceability of any patent that claims the biological product or a use of the biological product." 42 U.S.C.

Government recognizes an additional avenue of relief when it states that an innovator could "immediately bring suit under 35 U.S.C. § 281 for patent infringement." *Amicus* Br. of the United States at 13.

Where an innovator brings an action under any of these provisions, the district court is well within its authority to order the applicant to provide the disclosures required by section 262(*l*)(2)(A). It is "well settled" that "federal courts may use any available remedy" to enforce federal rights. *Barnes v. Gorman*, 536 U.S. 181, 189 (2002) (quoting *Bell v. Hood*, 327 U.S. 678, 684 (1946)); *see also Franklin v. Gwinnett Cnty. Pub. Sch.*, 503 U.S. 60, 71 (1992) ("[T]he federal courts have the power to award any appropriate relief in a cognizable cause of action brought pursuant to a federal statute."). Although the BPCIA does not expressly authorize such relief, that does not mean it is not available. "[W]hen all that a plaintiff seeks is to enjoin an unlawful act, there is no need for express statutory authorization; 'absent the clearest command to the contrary from Congress, federal courts retain their equitable power to issue injunctions in suits over which they have jurisdiction.'" *Sterk v. Redbox Automated Retail, LLC*, 672 F.3d 535, 539 (7th Cir. 2012) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 705 (1979)); *see*

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§ 262(*l*)(9)(C). The second provision treats the failure to disclose the required information under section 262(*l*)(2)(A) as "an artificial 'act of infringement' of 'a patent that could be identified' pursuant to paragraph (*l*)(3)(A)(i)." Pet. App. 16a (quoting 35 U.S.C. § 271(e)(2)(C)(ii)).

also Holland v. Florida, 560 U.S. 631, 645 (2010) ("[W]e will not construe a statute to displace courts' traditional equitable authority absent the clearest command") (alteration and internal quotation marks omitted).

Requiring compliance with the BPCIA's procedures is both necessary and appropriate in aid of the district court's jurisdiction over the patent infringement or declaratory action authorized by the statute. The purpose of the statutory disclosure procedures is to identify, and narrow, issues for eventual patent litigation through pre-litigation disclosure and discovery. A district court has every right to order compliance with these procedures to assure itself that the dispute has been sharpened for resolution, as Congress intended, and to reduce any unnecessary burdens on the court caused by non-compliance. *See, e.g., Zenith Elecs. Corp. v. United States*, 884 F.2d 556, 562 (Fed. Cir. 1989) (authority under All Writs Act to enjoin conduct that "would impinge upon and interfere with" court's review of case before it); *Virgin Islands v. Fahie*, 419 F.3d 249, 258 (3rd Cir. 2005) ("[C]ourts' supervisory powers are broad and include implementing remedies for violations of recognized rights.").

Ultimately, an applicant cannot avoid having to provide the disclosures that section 262(*l*)(A)(2) requires. As a result, the question is not *whether* those disclosures must be provided, but *when*. Under the BPCIA, the applicant has a mandatory obligation to provide those disclosures "[n]ot later than 20 days" after learning that its application has been accepted for review. 42 U.S.C. § 262(*l*)(2). If

the applicant violates section 262(*l*)(A)(2) by failing to provide the requisite disclosures, the innovator can then bring suit under the BPCIA and/or the patent statute, and in such an action the court can order the applicant to provide the disclosures required under section 262(*l*)(2)(A).

CONCLUSION

This Court should hold: (1) that a "notice of commercial marketing" under 42 U.S.C. 262(*l*)(8)(A) must be provided after a biological product has been licensed under subsection (k) and that courts may enforce this requirement by enjoining the sale of a biosimilar product for 180 days after effective notice is provided; and (2) that section 262(*l*)(2)(A)'s disclosure requirements are mandatory and may be judicially enforced.

Dated: March 17, 2017

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RECORD AND BRIEFS.

Supreme Court, U.S.
FILED
FEB 17 2017
OFFICE OF THE CLERK

Nos. 15-1039 and 15-1195

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner, Cross-Respondent,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents, Cross-Petitioners.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* MYLAN INC. IN SUPPORT OF PETITIONER, CROSS-RESPONDENT SANDOZ INC.

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INTEREST OF THE *AMICUS CURIAE*[1]

Mylan is one of the world's leading pharmaceutical companies. Mylan Inc.'s subsidiaries have filed and received approval for hundreds of Abbreviated New Drug Applications for generic drugs. With sales in approximately 165 countries and territories, Mylan is dedicated to providing greater access to high-quality, lower-priced medicines.

Mylan also has a robust pipeline of biologic products in development, both for the global marketplace and to be submitted for licensure in the United States as biosimilar products under the Biologics Price Competition and Innovation Act ("BPCIA"). Indeed, Mylan subsidiaries have submitted, and will submit, applications for licensure under subsection (k) of the BPCIA. Mylan is committed to providing patients expanded, and timely, access to high-quality and affordable biopharmaceuticals.

Mylan thus has a significant interest in the proper interpretation and application of the BPCIA, including ensuring that the BPCIA is not misused to create extra-statutory remedies, or misinterpreted to

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[1] All parties have consented to this filing. Correspondence reflecting the parties' consent has been lodged with the Clerk. No counsel for any party authored this brief in whole or in part. No party, counsel for any party, or person other than *amicus curiae* or its counsel made a monetary contribution to the preparation or submission of this brief.

create *de facto* exclusivities for Reference Product Sponsors ("RPS") contrary to the plain language of the statute and Congressional intent, thereby impermissibly delaying competition and consumer access to less expensive medicines.

SUMMARY OF ARGUMENT

The BPCIA reflects a careful and critical balance between innovation and price competition. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, Sec. 7001(b) ("It is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established."); *see also* Pet. App. 4a. On one side, Congress created an abbreviated licensure pathway that allows applicants to file a so-called abbreviated biologics licensure application ("aBLA") under 42 U.S.C. § 262(k) for biological products shown to be biosimilar to, or interchangeable with, a licensed reference product. In exchange, Congress granted RPSs certain periods of exclusivity which prevent applicants from filing an aBLA for a biosimilar product for four years from the date the reference product was licensed, and which delay ultimate eligibility for licensure of an aBLA product for 12 years from the date the reference product was licensed.

The Federal Circuit's decision regarding BPCIA Section 262(*l*)(8)(A) ignores the critical balance Congress struck by, *inter alia*, effectively extending the reference sponsor's 12-year exclusivity period by 180 days *every time* an aBLA applicant gives notice of commercial marketing under 42 U.S.C.

§ 262(*l*)(8)(A). The Federal Circuit's interpretation of Section 262(*l*)(8)(A) cannot stand: it runs afoul of the statutory language and Congressional intent by converting a simple notice provision into a *de facto* 180-day extension of market exclusivity; and preemptively awards an automatic 180-day preliminary injunction against every biosimilar sponsor without consideration of the merits or equities.

The Federal Circuit also ruled that the notice provision under Section 262(*l*)(8)(A) is a mandatory stand-alone provision, enforceable by an RPS; and that an aBLA applicant's notice of its commercial marketing cannot become effective until *after* FDA licensure. This interpretation fails on several levels. As an initial matter, only Congress can create a private right of action to enforce federal law, and it did not do so here. Even if Congress had created a private right of action (it did not), the Federal Circuit's decision conflicts with the express statutory language—and Congress' intent—which established a statutory mechanism to facilitate early *pre*-licensure patent resolution. The Federal Circuit based its decision on reasoning that reflects a fundamental misunderstanding of the detrimental impact it will have on all future aBLA applicants for years to come. That decision, by creating an automatic 180-day preliminary injunction against biosimilar sponsors without regard to the RPS' patent rights and the traditional requirements for equitable relief, further jettisons this Court's clear precedent.

The Federal Circuit's decision not only hurts aBLA applicants (who must wait 180 days to market their products, even after they have demonstrated biosimilarity to the relevant licensed reference products and all statutory exclusivities have expired), but also consumers and payors (who must wait an extra six months for a competing product to enter the market and drop prices). These costs capsize the balance Congress created in the BPCIA. This Court should reverse the Federal Circuit's decision regarding Section 262(*l*)(8)(A).

Finally, unlike its interpretation of Section 262(*l*)(8)(A), the Federal Circuit's construction of Section 262(*l*)(2)(A) is fully consistent with the express statutory language, as well as Congress' intent for these provisions and the BPCIA as a whole. This Court should thus affirm the Federal Circuit's decision regarding Section 262(*l*)(2)(A).

STATUTORY BACKGROUND

In 2010, Congress enacted the BPCIA to facilitate the entry of biosimilar drugs into the market by allowing for the submission of aBLAs for biological products shown to be biosimilar to, or interchangeable with, a licensed reference product. Among other things, the BPCIA added 42 U.S.C. § 262(k) to create the abbreviated regulatory pathway for the licensure of biosimilar and interchangeable products, and separately added 42 U.S.C. § 262(*l*) to provide a patent dispute-resolution process for these abbreviated applications.

Under the regulatory framework created by 42 U.S.C. § 262(k), Congress provided two exclusivity periods for the reference product: the *first* bars the submission of an aBLA for four years from the date the reference product was licensed; the *second* prevents FDA from granting approval to an aBLA product for 12 years from the date the reference product was licensed. 42 U.S.C. § 262(k)(7)(A), (B). These expressly defined periods of exclusivity apply independent of any patent rights held by the RPS.

Separate from creating this new regulatory approval pathway, Congress also created a mechanism for early resolution of patent disputes by allowing an RPS to assert infringement claims based solely on the submission of an aBLA and before FDA licensure occurs. 42 U.S.C. § 262(*l*); 35 U.S.C. § 271(e)(2)(C). This patent resolution mechanism is separate and distinct from the regulatory pathway that permits FDA licensure immediately upon expiration of the statutorily-determined periods of exclusivity. Under this regime, an RPS may seek to enjoin market entry by the competing biosimilar product, but only after filing an infringement action and making the requisite showing for a patent-based injunction.

The filing of an aBLA and notice of acceptance by FDA marks the beginning of the BPCIA's patent resolution procedures governed by 42 U.S.C. § 262(*l*). As detailed by the petitioner, Sandoz Inc., Congress set forth specific timeframes and sequencing prerequisites for each stage of the so-called "patent dance" that allows the aBLA applicant to opt out at any stage. *See* Pet. Br. at 12-16. Congress

recognized that an aBLA applicant may choose to participate in all, some, or none of the information exchanges under Sections 262(*l*)(2)-(8); Congress thus built into the statute specific ramifications for each action or inaction by the RPS or aBLA applicant. In sum, the scope and timing of patent litigation under the BPCIA is dictated by the actions or inactions of the parties at each stage of the information exchange process.

Relevant here, aBLA applicants who elect to disclose the information specified in Section (*l*)(2)(A), and engage in the information exchange, can control whether litigation occurs in one or two stages. More specifically, aBLA applicants may agree to immediately litigate all patents initially identified by both parties as reasonably giving rise to a claim of infringement, or choose to narrow the first stage of litigation to a select number of patents and leave other listed patents to be resolved in a second later stage of litigation. 42 U.S.C. § 262(*l*)(4)-(5). If an applicant chooses not to litigate all patents immediately, the aBLA applicant and RPS will exchange lists of patents that each believes should be litigated immediately, with the remainder to be potentially resolved in a second phase of litigation. 42 U.S.C. § 262(*l*)(5). The aBLA applicant controls the timing of the second stage of litigation, which cannot commence until after the aBLA applicant provides its 180-day notice of commercial marketing under Section 262(*l*)(8)(A). This notice lifts the bar on the parties' ability to litigate previously identified but unlitigated patents; allows the RPS to seek a preliminary injunction based on these patents; and

triggers the start of any second phase of litigation. 42 U.S.C. § 262(*l*)(8)(A). If, however, the aBLA applicant fails, or elects not, to give such notice, the BPCIA provides that the RPS, but not the aBLA applicant, has the right to bring an immediate action for declaratory judgment on any patents previously listed by the RPS. 42 U.S.C. § 262(*l*)(9)(B).

In contrast, where an aBLA applicant elects *not* to participate in the first step of the patent dance by providing its application within 20 days of notice of FDA acceptance, Section 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) give the *RPS* the immediate right to bring an infringement action against the aBLA applicant. Congress ensured that, whether an aBLA applicant elects to complete all, some, or none of the information exchange process, the RPS retains the ability to assert its patents and seek injunctive relief prior to the commercial marketing of the aBLA product.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION REGARDING SECTION 262(*l*)(8)(A) IS WRONG ON THE MERITS.

Under the Federal Circuit's decision, an RPS may privately enforce the BPCIA's notice provision and effectively extend the RPS' statutory market exclusivity for 180 days longer than Congress intended *every time* notice is given or required to be given. This result has no basis in the statute and, in fact, squarely conflicts with one of Congress' primary goals in creating the BPCIA—to facilitate the

resolution of patent disputes *before* aBLA licensure. If not reversed, the Federal Circuit's flawed statutory interpretation will remain unchecked and will continue to be applied by courts throughout the country; RPSs will benefit from an extra-statutory windfall that Congress never intended; and patients will suffer from delayed entry of more affordable biologic products.

A. The Federal Circuit's Decision Violates Clear Supreme Court Precedent By Creating A Private Right Of Action Where None Exists.

Under a plain reading of the statute, Section 262(*l*)(8)(A) is <u>*not*</u> a stand-alone notice provision that can be privately enforced. The Federal Circuit improperly fashioned a private right of action that allows an RPS to run into court to seek an order requiring the aBLA applicant to provide post-licensure notice of commercial marketing. The Federal Circuit's decision ignores the settled rule, repeatedly affirmed by this Court, that "private rights of action to enforce federal law must be created by Congress." *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). The Federal Circuit's decision on this issue cannot stand.

This Court has recognized that "where the text and structure of a statute provide no indication that Congress intends to create new individual rights, there is no basis for a private suit . . . under an implied right of action." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 286 (2002). *No* evidence exists here that Congress intended for an RPS to compel compliance

with the notice provision, let alone through a Federal Circuit-created extra-statutory injunction mandating post-licensure notice by an aBLA applicant. The majority (Judge Lourie joined by Judge Newman) did not even address this fundamental issue, much less identify any supporting authority or evidence that Congress created such an action. In reality, the BPCIA contains no express mechanism for litigants to privately enforce the notice provision under Section 262(*l*)(8)(A). In other words, just as the Federal Circuit found with respect to Section 262(*l*)(2)(A), here too, "the BPCIA has no other provision that grants a procedural right to compel compliance with the [notice] requirement of paragraph [262(*l*)(8)(A)]." Pet. App. 15a-16a. Nor can a private right of action be implied by the language or the structure of the Act. The statutory text suggests just the opposite.

First, the notice provision under Section 262(*l*)(8) "entirely lack[s] the sort of 'rights-creating' language critical to showing the requisite congressional intent to create new rights." *Gonzaga*, 536 U.S. at 287 (quoting *Alexander*, 532 U.S. at 288-89). Section 262(*l*)(8)(A) provides instructions to the aBLA applicant to provide advance notice of commercial marketing, while Section 262(*l*)(8)(B) provides that the RPS "may" seek a preliminary injunction where two preconditions to such an action have been met—(1) notice has been provided under subparagraph (A), and (2) the injunction is sought before the aBLA applicant has commercially marketed its biosimilar product. 42 U.S.C. § 262(*l*)(8)(A), (B). Separately, Section 262(*l*)(8)(C)

simply provides that the parties will "reasonably cooperate" to expedite any discovery deemed necessary in any such injunction action. *Id.* at § 262(*l*)(8)(C). Nowhere in Section 262(*l*)(8) does the statute provide the RPS with a "right" to notice, let alone a right to *enforce* the notice provision through an injunction proceeding.

Second, the BPCIA already contains express remedies where the aBLA applicant elects *not* to give notice of commercial marketing under Section 262(*l*)(8)(A). As the Federal Circuit acknowledges, where the aBLA applicant has provided its application to the RPS but elects not to provide notice of commercial marketing under Section 262(*l*)(8)(A), an RPS may immediately bring a declaratory judgment action under Section 262(*l*)(9)(B) for patent infringement, validity or enforceability of any patent included in the initial list described in paragraph (3)(A), including as provided under paragraph (7). 42 U.S.C. § 262(*l*)(9)(B); Pet. App. 25a ("[P]aragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A) . . . ."); Pet. App. 51a n.2 (Chen, J. dissenting).

Alternatively, as Judge Chen observes in his dissent, the statute provides that where the aBLA applicant elects *not* to provide its application to the RPS, under Section 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C), an RPS, but not the aBLA applicant, may bring a declaratory judgment action for patent infringement, validity or enforceability of *any* patent that claims the biological product or use of the

biological product. 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C); Pet. App. 51a (Chen, J. dissenting) ("Congress created the fallback provision of (*l*)(9)(C) for just these circumstances. An RPS does not need the remedy in (*l*)(9)(B) because (*l*)(9)(C) and § 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action when the (k) applicant fails to comply with (*l*)(2). At this point, the RPS possesses the statutory right to seek a preliminary injunction for any of its patents that 'could be identified pursuant to section [262](*l*)(3)(A)(i).'").

As this Court previously has acknowledged, "where a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. Nat'l Fed'n of Fed. Emps., Local 1263*, 489 U.S. 527, 533 (1989) (citing *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 19 (1979)). In such cases, absent strong evidence of contrary congressional intent, courts "are compelled to conclude that Congress provided precisely the remedies it considered appropriate." *Karahalios*, 489 U.S. at 533 (quoting *Middlesex Cty. Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 15 (1981)); *Alexander*, 532 U.S. at 290 ("The express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others."). This is true even where the statute may be interpreted as providing a benefit to those seeking to enforce it. *California v. Sierra Club*, 451 U.S. 287, 294 (1981) ("The question is not simply who would benefit from the Act, but whether Congress intended to confer federal rights upon

those beneficiaries."); *Transamerica*, 444 U.S. at 24 ("[T]he mere fact that the statute was designed to protect advisers' clients does not require the implication of a private cause of action for damages on their behalf. The dispositive question remains whether Congress intended to create any such remedy." (citations omitted)). Indeed, "even where a statute is phrased in such explicit rights-creating terms, a plaintiff suing under an implied right of action still must show that the statute manifests an intent 'to create not just a private *right* but also a private *remedy*.'" *Gonzaga*, 536 U.S. at 284 (quoting *Alexander*, 532 U.S. at 286).

Here, Congress created the *sole* remedies for an alleged breach of Section 262(*l*)(8)(A) in Sections 262(*l*)(9)(B) and 262(*l*)(9)(C)—both of which provide the RPS with the right to assert its patents at pre-specified stages before the commercial marketing of the biosimilar. There is no indication whatsoever that Congress ever intended to provide any other remedies, including injunctive relief, for failure to provide effective notice of commercial marketing—particularly where such injunctive relief is divorced entirely from any claim of patent infringement. Indeed, just as the Federal Circuit found with respect to Section 262(*l*)(2)(A), "the BPCIA does not specify any non-patent-based remedies for a failure to comply with [Section 262(*l*)(8)(A)]." Pet. App. 17a. Thus, the Federal Circuit's decision cannot stand.

Finally, even though the Federal Circuit acknowledged "certain similarities" between the goals and procedures of the BPCIA and the Hatch-

Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, Pet. App. 5a, the Federal Circuit's decision here is wholly inconsistent with its prior decisions considering whether a private right of action can be implied under Hatch-Waxman.

In case after case under Hatch-Waxman, the Federal Circuit found that a private right may *not* be implied. For example, as originally enacted, Hatch-Waxman required a drug company seeking to market a generic drug product prior to expiration of a relevant patent to provide the patentee with "*a detailed statement* of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." 21 U.S.C. § 355(j)(2)(B) (1984) (emphasis added)). In an appeal before the Federal Circuit, the brand drug company sought relief based upon the alleged insufficiency of the generic company's "detailed statement." *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775 (Fed. Cir. 2002). There, the Federal Circuit correctly held that "§ 355(j)(2)(B) cannot be enforced by a private party in a patent infringement action . . . ." *Id.* at 777.

As another example, as originally enacted, Hatch-Waxman required brand drug companies to submit "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug . . . ." 21 U.S.C. § 355(b)(1) (1984). Because the submission of patent information under the original statutory scheme almost certainly led to delays in generic drug approvals, various brand companies submitted information for patents that did not meet the statutory criteria for submission.

Some generic companies responded to such statutory violations by bringing claims seeking to have improperly submitted patents removed, or "delisted," from FDA's official list of patents. Time after time, the Federal Circuit held that no private right of action existed for delisting a patent that did not meet the statutory criteria for submission to FDA. *See, e.g.*, *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1332 (Fed. Cir. 2001) (holding that no private right of action existed for delisting a patent from the Orange Book because there is "nothing in the Hatch-Waxman Amendments to alter the statement in section 337(a) of the FFDCA that 'all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'"), *superseded by statute*, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified at 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2003)); *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002) (holding that "the district court ha[d] no authority in the infringement action . . . to shorten the thirty-month stay because of allegedly improper conduct before the FDA").

The facts presented here compel the same result—the BPCIA does not expressly or implicitly create a private right of action to enforce the notice provision of Section 262(*l*)(8)(A). *See also* United States Amicus Br. at 19-20. For this reason alone, this Court should reverse the Federal Circuit's decision.

B. Even If A Private Right Of Action Existed, The Federal Circuit's Decision Runs Afoul Of The BPCIA's Express Text And Purpose, And Thus Cannot Stand.

The Federal Circuit's interpretation of Section 262(*l*)(8)(A)—requiring mandatory post-licensure notice and effectively imposing an automatic 180-day injunction—cannot be squared with the BPCIA's text or purpose. The statutory text and purpose compel a construction under which notice of commercial marketing can be effective *before* FDA licensure, and the RPS may obtain an injunction to delay biosimilar marketing only *after* the RPS has met the traditional requirements of equitable relief.

1. The Federal Circuit's Decision Is Contrary To The BPCIA's Express Text.

The sole qualification the statute offers with respect to pre-marketing notice is that "[t]he subsection (k) applicant shall provide notice . . . not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). The plain language of the BPCIA does not—as the Federal Circuit held—require notice to be sent post-FDA licensure. Congress, rather, established the *latest* date on which a biosimiliar may give notice, not the *earliest* (as the Federal Circuit impermissibly construed it). The "not later than" restriction is the *only* limit that the statute imposes on the timing of pre-marketing notice. Thus, by its express "not later than" terms, Section

262(*l*)(8)(A) directly addresses the timing of pre-marketing notice and explicitly permits *pre*-licensure notice. To find otherwise, the Federal Circuit improperly construed the plain language of the statute, and its interpretation cannot stand. *See* Pet. Br. at 31-32; United States Amicus Br. at 13-20; Pet. App. 18a-21a.

Moreover, by holding that Section 262(*l*)(8)(A) is a standalone provision requiring mandatory notice after licensure, the majority's interpretation provides, as dissenting Judge Chen explained, "an inherent right to an automatic 180-day injunction," a result wholly at odds with the express language of the immediately succeeding section, Section 262(*l*)(8)(B). Pet. App. 52a (Chen, J., dissenting). Section 262(*l*)(8)(B) allows the RPS, "[a]fter receiving the notice," solely to "*seek* a preliminary injunction prohibiting the [aBLA] applicant from engaging in the commercial manufacture or sale of such biological product . . ." based on any patent(s) listed in the initial exchanges during the "patent dance" but not selected for litigation (*i.e.*, the so-called "phase-two patents"). 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). These statutory notice provisions may not be construed in isolation. *Samantar v. Yousuf*, 560 U.S. 305, 319 (2010). Congress did not create an automatic right to a 180-day injunction through Section 262(*l*)(8)(A); it granted, through Section 262(*l*)(8)(B), the more limited right for an RPS to "seek" such an injunction only, which the RPS may obtain solely by making the required showing on the merits and equities.

The Federal Circuit's interpretation of Section 262(*l*)(8)(A) as requiring mandatory post-licensure notice runs contrary to the plain language of the statute and should be reversed on this basis alone.

2. The Federal Circuit's Decision Conflicts With The BPCIA's Structure And Purpose.

The Federal Circuit's decision rests on a fundamental misunderstanding of the practical consequences of mandating notice *after* licensure but *before* commercial marketing. The Federal Circuit acknowledges that its mandatory post-licensure notice interpretation grants RPSs 180 days of exclusivity found nowhere in the statute, but asserts "[t]hat [the] extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." Pet. App. 22a. As the petitioner has explained, however, this assertion misunderstands, if not completely ignores, the timing consequences of mandating *post*-licensure notice of commercial marketing. *See* Pet. Br. at 58-60.

The fact is that licensure cannot occur until the RPS' 12-year exclusivity expires. *See* U.S. FOOD & DRUG ADMIN., REFERENCE PRODUCT EXCLUSIVITY FOR BIOLOGICAL PRODUCTS FILED UNDER SECTION 351(a) OF THE PHS ACT: DRAFT GUIDANCE at 2 (Aug. 2014) (42 U.S.C. § 262(k)(7) states a "period of time in which . . . *FDA is not permitted to license* a 351(k) [biosimilar] application") (emphasis added). Consequently, the Federal Circuit's decision mandating notification only *after* FDA grants

licensure inevitably and necessarily extends the statutory 12-year exclusivity in *all* instances where notice is given. Judge Chen identified precisely this problem in his dissent, discussing how the majority's mandatory post-licensure notice interpretation gives the RPS "an extra-statutory exclusivity windfall" in the form of "an inherent right to an automatic 180-day injunction," even in instances where no patent issues remain unresolved. Pet. App. 44a, 52a (Chen, J., dissenting).

The Federal Circuit's creation of a 180-day *de facto* exclusivity period disrupts the complex and careful statutory bargain Congress enacted. Congress granted reference products 12 years of exclusivity (regardless of patent protection) in exchange for the biosimilar applicant's reliance on the safety and efficacy of the reference product. *See* 42 U.S.C. § 262(k)(7)(A). If, as Judge Chen correctly observed, Congress had wanted to create an automatic stay of approval, it knew how to do so. Pet. App. 52a-53a (Chen, J., dissenting); *see, e.g.*, 21 U.S.C. § 355(j)(5)(B)(iii) (thirty-month stay provision under Hatch-Waxman). Congress did <u>not</u>, by the express language of the statute, do so here. Similarly, when Congress wants to grant additional periods of exclusivity, it *expressly* grants them. *See, e.g.*, 42 U.S.C. § 262(m)(2)(A) (granting "12 years and 6 months" of non-patent exclusivity to sponsors providing pediatric data); 21 U.S.C. § 360cc (granting seven (7) years of non-patent exclusivity for orphan drugs). Congress did <u>not</u> do so here.

By judicially-creating an additional 180-day exclusivity period for the RPS, the Federal Circuit

runs afoul of the structure of the BPCIA. Again, independent of any patent rights, Congress granted reference products four years of exclusivity before an aBLA may be submitted *and* 12 years of exclusivity before an aBLA may be licensed. *See* 42 U.S.C. § 262(k)(7)(A), (B). These exclusivity provisions under Section (k)(7) (entitled "Exclusivity for reference product") are separate from the patent resolution procedures established in Section (*l*) (entitled "Patents")—the section which includes the notice of commercial marketing provision under paragraph (*l*)(8)(A). Despite Congress' clear intent to have such notice revolve around the resolution of patent disputes by including it in Section (*l*) and tying such notice to the start of the second phase of litigation, the Federal Circuit erroneously converts the notice provision into an extra 180-day period of *de facto* exclusivity regardless of the RPS' patent rights.

Furthermore, the Federal Circuit's interpretation is at odds with the BPCIA's broader purpose. As the majority acknowledges, "[t]he BPCIA amended the Patent Act to create an artificial 'act of infringement' and to allow infringement suits based on a biosimilar application *prior to FDA approval* and prior to the marketing of the biological product." Pet. App. 6a. (emphasis added). Yet, the Federal Circuit's decision now creates a mandatory 180-day *post*-licensure waiting period to purportedly provide the RPS with a "defined statutory window" during which the RPS may assert any remaining patent claims. Pet. App. 21a. If Congress wanted biosimilar patent suits postponed until *after* FDA licensure, Congress would

not have needed to create an artificial act of infringement under 35 U.S.C. § 271(e)(2)(C), which it did indeed do. Moreover, there already is a statutory mechanism to resolve patent disputes post-licensure: the RPS may bring a declaratory judgment action and/or seek a preliminary injunction under other sections of the Patent Act such as 35 U.S.C. § 271(a) and/or (g). 35 U.S.C. § 271(a), (g). By including Section 262(*l*)(8)(A)'s pre-commercial marketing notice, Congress afforded the parties a mechanism to engage in *pre*-licensure patent litigation over patents that had been previously identified by the parties but were not a part of the phase-one litigation—a mechanism which RPSs and would-be biosimilar applicants alike endorsed. During Congressional testimony presented during enactment of the BPCIA, a representative of the Biotechnology Industry Organization, which includes among its members RPSs like Amgen, confirmed this, testifying that:

> Nearly all stakeholders in the biosimilar debates support inclusion of procedures to identify and resolve patent issues *before a biosimilar is approved* and placed on the market. . . . Providing a way to start patent litigation before the biosimilar product is on the market (*i.e.*, during the data exclusivity period of the innovator and while the biosimilar product cannot be marketed because it is undergoing review by the FDA) will benefit patients, physicians, insurers, follow-on manufacturers and innovators alike.

(Jeffrey P. Kushan, Prepared Statement On Behalf Of Biotechnology Indus. Org. on *Biologics and Biosimilars: Balancing Incentives for Innovation, Before the H.R. Subcomm. on Courts & Competition Policy, Comm. on the Judiciary*, 111th Cong. (July 14, 2009), http://judiciary.house.gov/_files/hearings/pdf/Kushan090714.pdf) (emphasis added).

Interpreting Section 262(*l*)(8)(A)'s notice provision to delay litigation until *after* licensure frustrates Congress' goals of facilitating early patent resolution. Moreover, regardless of whether notice is given after licensure or at least 180 days before licensure, there still exists a "defined statutory window" within which any so-called "phase-two" patent claims may be asserted. Pet. App. 21a.

The Federal Circuit defends its decision by asserting that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." Pet. App. 21a. According to the Federal Circuit, Congress meant for notice to follow licensure so that "the product, its therapeutic uses, and its manufacturing processes are fixed." *Id.* But this explanation contradicts the Federal Circuit's own statements, made just seven months earlier in another BPCIA dispute involving the same parties and Amgen's patents covering its Enbrel® product. There, the Federal Circuit stated that the aBLA application itself "circumscribes and dominates the assessment of potential infringement." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014).

The statute provides no basis for holding an RPS' injunction efforts at bay until after licensure, given that Congress *created* the pathway by which an RPS may initiate suit—*pre*-licensure—after the parties engage in the "patent dance" (or immediately after an aBLA applicant reveals that it will not disclose its application or otherwise participate in the "patent dance"). In fact, following the Federal Circuit's reasoning to its logical end, if a crystalized controversy only exists after the biosimilar product, its therapeutic uses, and manufacturing processes are fixed by way of licensure, then all pre-licensure litigation is premature. This view—which flows directly from the Federal Circuit's reasoning—is, of course, as illogical as it is unsupported. No one disputes that a federal court has jurisdiction to hear a case brought under the BPCIA and to issue appropriate injunction(s) if the RPS and the aBLA applicant engage in the patent dance and agree to immediately litigate patents identified pursuant to the patent exchange process—even if that litigation begins and ends years before licensure. *See generally* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6); 42 U.S.C. § 262(*l*)(4), (*l*)(6). Indeed, to date, Amgen has initiated several independent BPCIA actions, all filed prior to aBLA licensure, to assert various patent claims. *See Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741 (N.D. Cal. filed Oct. 24, 2014); *Amgen Inc. v. Apotex Inc.*, No. 15-cv-61631 (S.D. Fla. filed Aug. 6, 2015); *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839 (D. Del. filed Sept. 18, 2015); *Amgen Inc. v. Apotex Inc.*, No. 15-cv-62081 (S.D. Fla. filed Oct. 2, 2015); *Immunnex Corp. v. Sandoz, Inc.*, No. 16-cv-01118 (D.N.J. filed Feb. 26, 2016).

The same is true where the aBLA applicant refuses to disclose its application. In that instance, as the Federal Circuit recognizes, the RPS is entitled under Section 262(*l*)(9)(C) to file an immediate declaratory judgment action on "any patent that claims the biological product or a use of the biological product." 42 U.S.C. § 262(*l*)(9)(C). There is no indication that Congress believed the issues for purportedly relevant patents that were not initially selected for immediate litigation during the patent exchange process (*i.e.*, the so-called "phase-two" patents) are any less "crystallized," and must be resolved after licensure. Nor is there any indication that Congress intended for the parties to wait—possibly years—to conclude litigation over these phase-two patents, which only delays patent certainty for the aBLA applicant.

Finally, another inherent problem with the Federal Circuit's decision is that, under its interpretation, an aBLA applicant's launch will necessarily be delayed by 180 days even where there are *no* relevant patents, all patents have *expired* by the time of licensure, or the parties have fully *resolved* their patent dispute before licensure. Indeed, it could easily be the case that, by the time an aBLA applicant is eligible for licensure, all relevant patents have expired, or such patents have already been fully litigated and all disputes resolved. Such impermissible launch delays become all the more likely as new aBLAs are filed immediately after the four-year data exclusivity period expires, where the parties have up to eight years to resolve disputes

over the RPS' patents before the aBLA may be eligible for licensure.

This Court should reverse the Federal Circuit's decision, thus ensuring that the BPCIA's early patent resolution mechanism is allowed to work as Congress intended.

C. Even If A Private Right Of Action Existed, The Federal Circuit's Decision Violates This Court's Precedent By Creating An Automatic 180-Day Injunction, Without Consideration Of The Equities.

The Federal Circuit's decision must also be set aside because it effectively grants an automatic 180-day injunction in all circumstances, without any findings that satisfy the traditional requirements for equitable relief, in blatant violation of this Court's precedent in *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006), which rejects any kind of "general rule" for an automatic injunction under the Patent Act. 547 U.S. at 393-94. As this Court held, "a major departure from the long tradition of equity practice should not be lightly implied." *Id.* at 391 (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 320 (1982)). This Court cautioned against "broad classifications" or "categorical rule[s]" when applying the traditional principles of equity and "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows" a statutory violation. *eBay*, 547 U.S. 392-93.

The Federal Circuit previously has recognized this Court's directive when it overruled its general practice of issuing permanent injunctions, without consideration of the traditional principles of equity, upon adjudication of infringement and validity under the Patent Act. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1148 (Fed. Cir. 2011); *see also SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 807 F.3d 1311, 1332 (Fed. Cir. 2015) ("Likewise, *eBay* clarifies that a patentee is not automatically entitled to an injunction—the patentee must prove that the equities favor an injunction." (citing *eBay*, 547 U.S. at 392)). Despite understanding and applying this Court's precedent in other circumstances, the Federal Circuit, here, effectively rewrote the notice provision as imposing an automatic injunction without any consideration of the equities.

There is no basis in the BPCIA, equity, or common sense to delay patient access to lower-cost biosimilars for even a day—much less 180 days—without a full consideration of the equities and justification on the merits of a patent claim. As discussed above, under the majority's interpretation, this automatic injunction would apply in all circumstances, independent of any evaluation of infringement and, indeed, independent of the existence of any patent protection whatsoever. This Court should, and indeed must, reverse the Federal Circuit to ensure that this Court's precedent is followed and injunctive relief against an aBLA applicant is awarded only where the traditional requirements for equitable relief are met.

II. THE BPCIA'S EXPRESS LANGUAGE REQUIRES THE CONSTRUCTION OF SECTION 262(*l*)(2)(A) ARTICULATED BY THE FEDERAL CIRCUIT.

After an exhaustive review of the relevant BPCIA provisions, the Federal Circuit correctly concluded that, under a plain reading of the statute, an aBLA applicant that fails to provide the RPS with information under Section 262(*l*)(2)(A) does "not violate the BPCIA," but rather takes "a path expressly contemplated by the BPCIA . . . ." Pet. App. 18a. Further, when an aBLA applicant does not provide the RPS with information under Section 262(*l*)(2)(A), the Federal Circuit held that "42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e) expressly provide *the only remedies* as those being based on a claim of patent infringement." Pet. App. 18a (emphasis added). The Federal Circuit could reach no other lawful result given the express statutory language.

Section 262(*l*)(2)(A) provides that:

> Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.

42 U.S.C. § 262(*l*)(2)(A). The RPS here, Amgen, makes much of the "shall" language in this statutory provision to support its contention that failing to provide the identified information constitutes a statutory violation. *See, e.g.*, Amgen Cond. Cross-Pet. at 4-6. But as the Federal Circuit found, the "shall" language in Section 262(*l*)(2)(A) does not render an aBLA applicant's decision to withhold the specified information a statutory violation. Indeed, the Federal Circuit recognized that the BPCIA expressly contemplates that an aBLA applicant may elect to withhold the information identified in Section 262(*l*)(2)(A). Pet. App. 12a-18a.

In those instances where an aBLA applicant elects to withhold the information identified in Section 262(*l*)(2)(A), the BPCIA expressly specifies patent-based remedies as the sole remedies available to the RPS. In the Federal Circuit's words: "the BPCIA explicitly contemplates that a subsection (k) applicant might fail to disclose the required information by the statutory deadline. It specifically sets forth the consequence for such failure: the RPS may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)." Pet. App. 15a. Section 262(*l*)(9)(C) provides:

> If a subsection (k) applicant *fails to provide the application and information required under paragraph (2)(A),* the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of *infringement, validity, or enforceability of any patent* that claims

> the biological product or a use of the biological product.

42 U.S.C. § 262(*l*)(9)(C) (emphases added). And 35 U.S.C. § 271(e)(2)(C)(ii), as amended by the BPCIA, provides:

> It shall be an act of infringement to submit . . . if the applicant for the application *fails to provide the application and information required* under section 351(*l*)(2)(A) of such Act [*i.e.*, 42 U.S.C. § 262(*l*)(2)(A)], an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act.

35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added). In addition, 35 U.S.C. § 271(e)(4) expressly identifies "the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2) . . . ." 35 U.S.C. § 271(e)(4) (emphasis added); *see also* Pet. App. 18a.

As the Federal Circuit acknowledged, "both 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) are premised on a claim of patent infringement, and *the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (l)(2)(A).*" Pet. App. 17a (emphasis added); *see also* Pet. App. 15a-16a ("[T]he BPCIA has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A).").

Thus, as the Federal Circuit pointed out, mandating compliance with Section 262(*l*)(2)(A) in all instances "would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous." Pet. App. 17a (citing *Marx v. Gen. Revenue Corp.*, 568 U.S. ——, 133 S. Ct. 1166, 1178, (2013); *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (cited quotations omitted)).

Because the BPCIA on its face expressly contemplates that an aBLA applicant may elect to withhold the information identified in Section 262(*l*)(2)(A), and because the statute contains patent-based remedies as the sole remedy available to RPSs that do not receive the information identified in Section 262(*l*)(2)(A) from the aBLA applicant, the Federal Circuit's decision on these issues should stand.

CONCLUSION

With respect to Section 262(*l*)(8)(A), the Federal Circuit's decision runs afoul of the plain language of the statute, as well as the purpose of the BPCIA. If left in place, that decision inevitably will deny patients lower-priced biologic medications, *in all cases*, longer than Congress intended, thus upsetting the careful balance of the BPCIA. The Federal Circuit's decision should be reversed. With respect to Section 262(*l*)(2)(A), the Federal Circuit correctly concluded that the BPCIA expressly contemplates that aBLA applicants may elect not to provide the RPS with information under Section 262(*l*)(2)(A), and in such instances, "42 U.S.C. § 262(*l*)(9)(C) and 35

U.S.C. § 271(e) expressly provide the only remedies" available to the RPS. Its decision on this issue should be affirmed.

Respectfully submitted,

FEBRUARY 17, 2017

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No. 15-1039

FILED
FEB 17 2017
OFFICE OF THE CLERK
SUPREME COURT, U.S.

In The
Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICI CURIAE PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, AND HEALTHCARE SUPPLY CHAIN ASSOCIATION IN SUPPORT OF PETITIONER

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This brief is submitted on behalf of the Pharmaceutical Care Management Association, National Association of Chain Drug Stores, and Healthcare Supply Chain Association, as *amici curiae* in support of Petitioner Sandoz Inc.[1]

INTEREST OF THE AMICI CURIAE

Amici curiae collectively represent many of the organizations involved in getting prescription medicines from manufacturers to patients, including organizations and entities that purchase prescription medicines on behalf of patients, develop and maintain drug formularies, process insurance claims, negotiate contracts for prescription drugs with pharmacies and drug manufacturers, dispense prescription medicines to patients, and aid patients in taking their medicines correctly and safely.

The Healthcare Supply Chain Association (HSCA) is a non-profit association that represents fourteen group purchasing organizations (GPOs) for pharmaceuticals and other products and services used by healthcare providers. GPOs negotiate contracts with healthcare manufacturers and distributors on behalf of group members, harnessing their members' collective purchasing power. They also help group members manage complex purchasing systems to improve efficiency and reduce errors. Group members include for-profit and non-

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[1] The parties have consented in writing to the filing of this *amicus curiae* brief. No counsel for any party authored this brief in whole or in part, and no person or entity, other than amici curiae or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

profit corporations, associations, multi-hospital systems, clinics, surgery centers, nursing homes, and healthcare provider alliances. As of 2015, over ninety-eight percent of all non-profit, non-governmental hospitals participate in at least one GPO. On average, seventy-two percent of all hospital purchases are made through GPO contracts. HSCA works to facilitate an open dialogue between GPOs regarding best procurement practices, and works on behalf of GPOs to ensure fair and efficient procurement practices in an open and competitive market within the health industry.

The Pharmaceutical Care Management Association is a non-profit national trade association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program, state government employee plans, managed Medicaid plans, and others. PBMs also provide services to plan sponsors which can include formulary development and maintenance, as well as prospective and retrospective drug utilization reviews. Most sophisticated purchasers of healthcare products in the United States utilize the services of a PBM.

The National Association of Chain Drug Stores (NACDS) is a 501(c)(6) non-profit trade association. Its mission includes advancing the interests and objectives of chain community pharmacies, such as supporting their role as

healthcare providers. NACDS membership consists of chain community pharmacy companies – including traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four pharmacies to national companies. NACDS has more than 100 members which, collectively, operate 40,000 pharmacies in the United States and employ 178,000 pharmacists. NACDS members fill more than three billion prescriptions annually, including prescriptions for biologics, and aid patients in taking their medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

As trade associations representing industry actors involved in the distribution of prescription medicines and care of patients nationwide, *amici* have a significant interest in, and a unique perspective on, the important issue of delay to market of biosimilars raised in this case. If it stands, the U.S. Court of Appeals for the Federal Circuit's decision will deny patients access to biosimilars licensed by the Food and Drug Administration (FDA) for 180 days (approximately six months), without regard to whether a legitimate patent claim actually exists regarding the biosimilar in question. Each *amicus* represents members with a strong interest in ensuring that patients in the United States receive the most cost-efficient and effective drugs prescribed without undue delay. *Amici* believe that their perspectives will assist the Court in resolving this case, in accordance with Sup. Ct. R. 37.1.

SUMMARY OF THE ARGUMENT

In passing the Biologics Price Competition and Innovation Act (BPCIA), Congress struck a balance between medical innovation and consumer access. The Federal Circuit has misinterpreted the text of the BPCIA, at 42 U.S.C. § 262(*l*)(8)(A), and in so doing has conferred an unintended benefit on innovator drug sponsors – 180 days of additional market exclusivity – at the expense of the significant consumer interest in access to effective biologics. *Amici* urge the Court to reject the Federal Circuit's interpretation of § 262(*l*)(8)(A).

The importance of biosimilars to the public interest can hardly be overstated. Biologics are some of the most promising medicines available today, and they are also some of the most expensive. They represent a significant and growing percentage of total prescription drug costs for drug purchasers and payers throughout the country, both public and private. The high cost of these products is also experienced directly by patients in the form of co-insurance or copays to cover some portion of the drug price, or in the form of rising insurance premiums. For many individual patients, the costs are untenable.

Amici are concerned that six additional months without biosimilar competition will place a significant burden on payers, purchasers, and pharmacies, and will negatively affect patients' access to treatment and affordable health care. The market introduction of similar or interchangeable products can be expected to drive average prices down, thereby improving patient access. Any delay

to market competition will necessarily delay that effect. For patients who take a medicine that may cost tens of thousands of dollars per year, and for payers and drug purchasers who bear much of that cost, six months of lower prices would make a meaningful difference.

In light of the sacrifice it represents to the public's interest in effective, lower-cost medicines, the Federal Circuit's decision is particularly objectionable because it is not required – or even supported – by the language of the statute or its purpose. The text of 42 U.S.C. § 262(*l*)(8)(A) requires only that notice be provided "not later than 180 days before the date of the first commercial marketing." The Federal Circuit created an implied requirement that notice be provided only *after* FDA has licensed the biosimilar at issue. But this reading conflicts with the plain language of § 262(*l*)(8), which refers to the "applicant" both in describing (1) the entity required to give 180-day notice, and (2) the entity against whom a reference biologic sponsor must seek an injunction. In plain English, as well as in the statute's specific parlance, the term "applicant" describes an entity that has filed a Biologics License Application (BLA) *before* that BLA has been approved by FDA. Once FDA has approved the BLA, the same entity is called the "holder" or "sponsor" of the BLA, not an "applicant."

Nor does the statutory context support the Federal Circuit's interpretation of 42 U.S.C. § 262(*l*)(8)(A). The BPCIA sets forth a comprehensive procedure for patent litigation that allows the reference biologic sponsor to defend its patent rights effectively and efficiently. Considering that scheme

as a whole, the six months additional exclusivity inserted by the Federal Circuit is unnecessary to safeguard biologic sponsors' rights under the BPCIA and patent law.

ARGUMENT

I. The Circuit Court's Interpretation of 42 U.S.C. § 262(*l*)(8)(A) Conflicts with Congress' Intent and Is Not in the Public Interest.

The Federal Circuit's reading of 42 U.S.C. § 262(*l*)(8)(A) extends exclusivity for reference biologics by approximately six months, to *twelve-and-a-half* years. An additional six months of biologics exclusivity imposes significant costs throughout the drug supply chain that ultimately harm consumer interests and are not necessary to safeguard patent rights and encourage innovation. This result conflicts with Congress' intent in passing the BPCIA. *See* BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010) ("It is the sense of the Senate that a biosimilars pathway *balancing innovation and consumer interests* should be established." (emphasis supplied)).

As stated above, *amici* represent actors throughout the pharmaceutical supply chain that have a common purpose of ensuring patient access to innovative and effective treatments at the lowest feasible cost. Absent competition, biologics represent a substantial and increasing portion of prescription drug costs borne by *amici*'s members organizations, and the patients they serve. Even a six-month delay in competition for these products can be expected to

impose significant costs on *amici* members and will negatively affect consumer access.

a. Six Months Additional Exclusivity Will Impose Significant Costs on Industry and Patients.

Biologics are some of the most costly drugs on the market. *See* Fed. Trade Comm'n, Transcript of Follow-On Biologics Workshop at 54 (Feb. 4, 2014), https://www.ftc.gov/system/files/documents/public_events/171301/140204biologicstranscript.pdf (Lee Purvis, AARP) ("The average annual cost of a branded biologic is estimated to be roughly 35,000 dollars right now. However, annual costs can range anywhere from 25,000 to 200,000 dollars or more."). These high prices, in combination with an increase in the number of biologics and number of indications for current biologicals, translate to a rapid growth in spending on biologics throughout the country. *See id.* at 53-54. In fact, spending on biologics increased from $67 billion in 2010 to $92 billion in 2013. *See* Alex Brill, *The Economic Viability of a U.S. Biosimilars Industry*, Matrix Global Advisors, 4 (Feb. 2015). Biologics accounted for thirty-three percent of all drug spending in 2015 for one public payer, the Ohio Public Employees Retirement System (OPERS). *See* Anna Rose Welch, *The Healthcare Purchaser's Role in Biosimilar Uptake*, Biosimilar Development (Oct. 18, 2016), https://www.biosimilardevelopment.com/doc/the-healthcare-purchaser-s-role-in-biosimilar-uptake-0001. The same public payer estimated that its percentage of drug spending attributed to biologics could rise to fifty percent by 2018. *Id.* On average, biologics are twenty-two times more expensive than traditional

(small molecule) drugs, and prices continue to increase. *See* Leigh Purvis, *A Sense of Déjà vu: The Debate Surrounding State Biosimilar Substitution Laws*, AARP Public Policy Institute, 1 (2014), www.aarp.org/content/dam/aarp/research/public_policy_institute/health/2014/the-debate-surrounding-state-biosimilar-substitution-laws-AARP-ppi-health.pdf.

Prior to passage of the BPCIA, the Congressional Budget Office estimated that the biosimilars pathway would reduce direct spending by the federal government by $5.9 billion over the 2009-2018 period, and would reduce total expenditures on biologics by $25 billion. *See* Cong. Budget Office, *Cost Estimate: Biologics Price Competition and Innovation Act of 2007*, 1 (June 25, 2008).[2] The same public payer mentioned above, the OPERS, estimated that it could save approximately $134 million over ten years with competition for biologics. *See* OPERS, Biosimilars Stakeholder Panel Presentation by Brian Lehman, Manager of Pharmacy and Benefits, 6, http://www.gphaonline.org/media/wysiwyg/Meetings/BIO_2016/Brian_Lehman.pdf (last visited Feb. 15, 2017). Assuming that six months additional exclusivity for every biological product will proportionately decrease expected savings from biosimilar competition within the same time periods, it will cost

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[2] Other industry analyses have estimated potential savings from biosimilars of between $1 billion and $108 billion over an approximately ten-year period. *See* Andrew W. Mulcahy et al., *The Cost Savings Potential of Biosimilar Drugs in the United States*, RAND Corp., 6 (2014). Even using the most conservative of these estimates—$1 billion—six months of additional exclusivity for each biosimilar translates to $50 million in lost savings for the U.S. healthcare market.

the federal government approximately $327.8 million between 2009-2018, and the U.S. healthcare market as a whole $1.4 billion. A single public payer, the OPERS, will lose approximately $6.7 million over ten years.

b. Six Months Additional Exclusivity Will Negatively Affect Patient Access to Biologics.

The high cost of biologics discussed above directly affects patients. *Amici* are concerned that patients' access to biologics in the six months following FDA licensure of a biosimilar will suffer as a result of the Federal Circuit's decision. *Amici* are also concerned that six months of additional costs associated with market exclusivity for reference biologics will increase the insurance premiums paid by all consumers, thereby negatively affecting those consumers' ability to afford health care.

A patient with rheumatoid arthritis may consume $30,000 to $40,000 worth of drug per year. *See* Fed. Trade Comm'n, Transcript of Follow-On Biologics Workshop at 267-68 (Feb. 4, 2014) (Harry Travis, Aetna); *see also* Harry Travis, Aetna, Presentation at Fed. Trade Comm'n Follow-On Biologics Workshop: Private Payor Perspective on Growth of Specialty Medicines and Naming (Feb. 4, 2014), https://www.ftc.gov/system/files/documents/public_events/FollowOn%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/travis.pdf. For such expensive drugs, even patients with drug benefits pay a significant percentage of the drug cost. *See, e.g.*, J. Yazdany et

al., *Coverage for High-Cost Specialty Drugs for Rheumatoid Arthritis in Medicare Part D*, 67 Arthritis Rheumatol. 1474 (2015) (reporting that Medicare beneficiaries pay on average 29.6% of the cost for biologics to treat rheumatoid arthritis). Manufacturer patient assistant programs often exclude patients whose income rises above a certain level, and even patients that might otherwise qualify are not always aware that they exist. *See* Joseph Walker, *Patients Struggle With High Drug Prices*, Wall Street J. (Dec. 31, 2015), https://www.wsj.com/articles/patients-struggle-with-high-drug-prices-1451557981. Medicare patients are prohibited from using some forms of manufacturer patient assistance programs. *Id.* (estimating that a Medicare patient with rheumatoid arthritis would pay nearly $5,000 out-of-pocket to treat the disease with a biologic in 2016). Faced with thousands of dollars in out-of-pocket costs for an effective biologic, patients are incentivized to choose less costly alternatives or forgo treatment altogether.

Introducing competition for a biologic provides a lower-cost alternative. *See* Andrew W. Mulcahy et al., *The Cost Savings Potential of Biosimilar Drugs in the United States*, RAND Corp., 3-4 (2014) ("Competition is the final and most important driver of cost-savings [for biologics]."). Even where the resulting price reductions are modest—10%, for example—the annual difference between $30,000 and $27,000 is not insignificant to consumers paying a significant portion of the cost of a drug out of pocket, and can affect the choice of therapy.

Lower cost options for biologics can also increase patient access to biologics indirectly by

affecting treatment guidelines for a particular condition. Treatment recommendations and guidelines take into account the cost of various treatment options because, as discussed above, the cost is expected to influence patients' decision-making. *See, e.g.*, Jasvinder A. Singh et al., *2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis*, Arthritis Care & Research, 4, 6, 7, 8, 10 (2016). The high cost of a particular therapy can contribute to its being recommended for use only in more advanced stages of a disease, or as a second- or third-line, rather than first-line, treatment. *See, e.g.*, *id.* at 10 ("The recommendation is **strong** despite the low quality of evidence because DMARD monotherapy [as compared to a TNFi biologic] is available as a less costly first-line therapy that has an extensive safety record . . . ."). Conversely, lowered costs for a biologic may result in more patients being prescribed that therapy at an earlier stage of their disease, or increase the number of patients who are prescribed the biologic as a first-line therapy. *See, e.g.*, Murray Aitken, *Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets*, IMS Inst. for Healthcare Informatics, 8-9 (Mar. 2016), http://www. imshealth.com/files/webIMSH%20Institute/Healthcare%20Briefs/Documents/IMS_Institute_Biosimilar_Brief_March_2016.pdf (citing the market experience of filgrastim in the United Kingdom, where the availability of a biosimilar changed official treatment guidelines, resulting in a greater number of patients being treated with filgrastim).

Even patients who do not require treatment with a biologic are negatively affected by the high

cost of biologics, because high prices for biologics cause the cost of health insurance to rise for all consumers. *See* Fed Trade Comm'n, Transcript of Follow-On Biologics Workshop at 265-66 (Feb. 4, 2014) (Harry Travis, Aetna). Conversely, lowered costs for biologics reduce the pressure on payers and purchasers, potentially creating room for procurement and coverage of additional therapies for patients.

II. The Plain Language of 42 U.S.C. § 262(*l*)(8)(A) Requires Notice Prior to Commercial Marketing, and Nothing More.

Contrary to the Federal Circuit's majority opinion, the plain language of 42 U.S.C. § 262(*l*)(8)(A) does not require the additional six months of exclusivity discussed above. In fact, the plain language of § 262(*l*)(8)(A) requires only that applicants provide notice 180 days before commercial marketing, nothing more.

Section 262(*l*)(8)(A) states:

> "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

Amici agree that the requirement to provide notice 180 days before launch is clear. However, the Federal Circuit determined that FDA licensure must occur *before* this notice is given; a requirement that

does not appear in the text, is not necessitated by the statutory context, and does not serve any rational legislative purpose.

The canons of statutory construction require courts to "presume that a legislature says in a statute what it means and means in a statute what it says there." *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). Contrary to the Federal Circuit's majority opinion, the plain language here does not limit how early notice may be sent. Rather, § 262(*l*)(8)(A) is explicitly limited to the *latest* time notice may be sent.

In fact, the language used in § 262(*l*)(8)(A) is consistent with the district court's interpretation that notice may be provided prior to licensing. *See Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741, 2015 U.S. Dist. LEXIS 34537, at *21-25 (N.D. Cal. Mar. 19, 2015). The text of § 262(*l*)(8)(A) states that a BLA "*applicant*" is to provide notice at least 180 days prior to marketing. A post-licensure sponsor is not an "applicant," but is a sponsor, or holder, of an approved application. If Congress intended the holder of an approved application to provide notice and wait 180 days before marketing, it would have expressly used the term "holder of an approved application" rather than "applicant." *See, e.g.*, 42 U.S.C. § 262(m)(3); *see also* 21 U.S.C. § 355(b)(3)(C)(ii) ("holder of the approved application"). Congress' use of the term "applicant" is dispositive. The statute must be read such that the *applicant* may give notice, and this can be achieved only if notice occurs prior to licensure.

In light of Congress' use of the term "applicant," the phrase "licensed under subsection (k)," 42 U.S.C. § 262(*l*)(8)(A), is more appropriately read to refer to the concept of "first commercial marketing," rather than that of notice. The phrase "biological product licensed under subsection (k)," *id.*, merely identifies the relevant product, which must be licensed upon first commercial marketing.

The Federal Circuit majority opinion reasons that Congress must have intended licensure as the start of a notice period because it otherwise would have used the phrase "the biological product that is the subject of the application" as it did elsewhere in the BPCIA. *Id.* § 262(*l*)(1)(D); *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1358 (Fed. Cir. 2015). However, the wording that the Federal Circuit's reasoning suggests—which would read "notice . . . not later than 180 days before the first commercial marketing of the biological product that is the subject of the application"—implies potential commercial marketing of an as-yet-unlicensed product; an absurd idea. Furthermore, the same argument regarding the phrasing Congress *should* have used can be made to discredit the Court's interpretation: had Congress intended the 180-day period in § 262(*l*)(8)(A) to begin only after FDA licensure, it could have included a provision explicitly prohibiting notice until that time. Thus, the Court's suggested alternative phrasing holds little weight, particularly when compared to the clear language that Congress did choose.

Finally, the Federal Circuit's interpretation of § 262(*l*)(8)(A)'s notice provision must be rejected

because it would render § 262(*l*)(8)(B) superfluous. *See Hibbs v. Winn*, 542 U.S. 88, 92 (2004) ("[T]he rule against superfluities instructs courts to interpret a statute to effectuate all its provisions, so that no part is rendered superfluous."). Section 262(*l*)(8)(B) requires a sponsor to affirmatively "*seek* a preliminary injunction prohibiting the . . . *applicant*" from marketing the biosimilar product based on its 180-day notice. 42 U.S.C. § 262(*l*)(8)(B) (emphasis supplied). The term "applicant," once again, indicates that the injunction in question would be sought in response to 180-day notice *before* an application is licensed by FDA. Moreover, if the Federal Circuit's interpretation of § 262(*l*)(8)(A) were correct, there would be no need to seek an injunction in addition to the automatic 180-day stay on marketing.

III. The Federal Circuit's Interpretation of 42 U.S.C. § 262(*l*)(8)(A) is Inconsistent With the Larger Context of § 262(*l*) and the BPCIA.

The Federal Circuit's determination that notice under § 262(*l*)(8)(A) must be given post-licensure also ignores the larger context of the notice requirement. Section 262(*l*)(8)(A) cannot be read in a vacuum. "It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989). The Federal Circuit's majority opinion misinterprets the statutory scheme, and the substance of the remaining statutory provisions.

According to the Federal Circuit majority opinion, notice after licensure is the only logical reading of § 262(*l*)(8)(A), because it allows reference product sponsors to understand the scope of the approved license and presents a "fully crystallized" controversy to determine whether to seek a preliminary injunction. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1358 (Fed. Cir. 2015). However, the Federal Circuit places too much emphasis on the notice provision, and not enough on the pre-notice litigation scheme.

Section 262(*l*), as a whole, sets out a procedure for the reference product sponsor to enforce its patent rights with respect to a biosimilar application. Specifically, § 262(*l*) details an information exchange leading up to a patent infringement suit expected to occur while the licensing application is under review. If the parties engage in the information exchange, the statutory procedure allows for the product sponsor to receive a copy of the biosimilar application and exchange patent information with the applicant, ultimately leading to a narrower patent infringement suit. Alternatively, the statute allows for commencement of a patent infringement action shortly following FDA's acceptance of the biosimilar licensing application for review.[3] With the exchange of patent information, opportunity for patent resolution negotiations, and availability of an infringement action outlined in § 262(*l*), the statute provides

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[3] The mere filing of the biosimilar application is an act of patent infringement and grounds for litigation prior to licensure under 35 U.S.C. § 271(e)(2)(C)(ii).

ample opportunity for a reference product sponsor to enforce its patent rights.

Section 262(*l*)(8)(A) exists as a safeguard to ensure that a reference product sponsor has enough time to seek an injunction if needed, and not as an additional period in which to make patent litigation decisions. Giving notice in excess of 180 days does not interfere with the sponsor's ability to seek an injunction, and in fact gives the sponsor *more* time in which to prepare to file, or file, for an injunction in advance of FDA approval of a biosimilar (a public act). If, on the other hand, an applicant guesses wrong regarding its expected FDA approval date and provides notice *less* than 180 days before that date, it is prohibited from entry until 180 days from notice has elapsed. There is, therefore, little logic to prohibiting notice until licensure; as long as notice is given at least 180 days prior to commercial marketing, the purpose of the statutory requirement is fulfilled.

The BPCIA also provides consequences for failure to provide timely notice under § 262(*l*)(8). Specifically, § 262(*l*)(9) permits the reference product sponsor to bring a declaratory infringement action against an applicant who fails to provide the required 180-day notice. The Federal Circuit's reading, however, imposes additional consequences even on those who comply with § 262(*l*) in full, in the form of a mandatory automatic 180-day stay on marketing.

This automatic stay, which occurs regardless of whether the biosimilar applicant has followed

each statutory requirement to the letter, and regardless of the merits of the patent claims at issue, is a windfall for reference product sponsors that serves no rational purpose for the protection of patent rights. This outcome is inconsistent with a statutory scheme designed to dispense quickly with patent litigation, and speed biosimilars to market.

CONCLUSION

For the reasons articulated above, *amici* respectfully request that the Court reverse the decision of the court below with respect to its interpretation of 42 U.S.C. § 262(*l*)(8)(A).

Respectfully submitted,

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